In the United States Court of Federal Claims

No. 16-1083 V
Filed: January 12, 2023
Re-issued: February 13, 2023[1]

J.S.,	)
Petitioner,	)
v.	)
SECRETARY OF HEALTH AND HUMAN SERVICES,	)
Respondent.	)

Robert J. Krakow, Law Office of Robert J. Krakow, P.C., for Petitioner.

Zoe Wade, Trial Attorney, United States Department of Justice, Torts Branch, Civil Division, Washington, D.C., for Respondent.

OPINION AND ORDER

MEYERS, Judge.

Pending before the Court is J.S.'s petition for review of the Chief Special Master's decision denying her claim for compensation under the National Vaccine Injury Compensation Program. Petitioner contends that she developed postural orthostatic tachycardia syndrome and inappropriate tachycardia from her vaccinations for Hepatitis A and human papillomavirus. The Chief Special Master concluded that Petitioner's medical records did not establish either injury by a preponderance of the evidence in this case; rather, the record indicated that it was more likely that other causes led to her symptoms. And the Chief Special Master concluded that Petitioner's theory that the vaccines at issue could cause the claimed injuries would, in any event, fail to establish causation in this case. Therefore, he denied Petitioner's claim. Because the Chief Special Master considered the evidence before him and articulated a reasoned basis for his conclusion, the Court sustains the Chief Special Master's decision denying entitlement.

I. FACTUAL AND PROCEDURAL BACKGROUND

[1] The Court initially filed this opinion under seal to allow the Parties to propose redactions. This re-issued opinion has incorporated the proposed redactions.

J.S. filed her petition for compensation under the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act"), 42 U.S.C. § 300aa-10 to 34 (2018), on August 30, 2016, alleging that receipt of the Hepatitis A ("Hep. A") and human papillomavirus ("HPV") vaccines caused her to develop inappropriate tachycardia,[2] autonomic dysfunction, and postural orthostatic tachycardia syndrome ("POTS").[3] ECF No. 1 ¶¶ 18-20 ("Pet."). Specifically, Petitioner claimed that she experienced "convulsions, shortness of breath, rapid heartbeat, . . . loss of feeling in her left leg[,] . . . pain in her joints, hyperventilation, heart palpitations, dizziness, [and] nausea, . . . [which] were caused-in-fact by her Gardasil vaccination received on August 19, 2015." Pet. at 3, ¶¶ 18-20. "Approximately one day after receiving the Gardasil HPV vaccination, and 16 days after receiving . . . a Hepatitis A vaccination, [Petitioner] experienced the onset of these conditions." ECF No. 114 at 2.

On April 20, 2017, Petitioner filed a motion to substitute counsel and a motion requesting interim attorney's fees and costs for her prior counsel. ECF Nos. 30 & 31. On June 7, 2017, Special Master Sanders issued an Order Deferring Resolution of Petitioner's request for fees, finding that it was speculative to determine whether the proceedings would become protracted at that stage, and it would have been "extremely difficult to determine the case's reasonable basis" without Respondent's position in the record. ECF No. 40 at 4-5. On August 2, 2018, Special Master Sanders issued a Decision Awarding Interim Attorney's Fees and Costs, with certain reductions to the amount requested. ECF No. 72.

Respondent filed its Rule 4(c) Report on June 12, 2017, asserting that, "Congress authorized the Vaccine Program to compensate only those individuals who can substantiate their claims either through a presumption of causation (i.e., proof of a Table case) or by proving a causal link between the alleged injuries and a covered vaccine[,] . . . [and] petitioner has not met her *prima facie* burden to show causation-in-fact . . . ." ECF No. 41 at 11. In response, Petitioner submitted "a 19-page memorandum, ECF No. 42, clarifying and correcting points contained in Respondent's Rule 4(c) Report[,] . . . [which] form[s], in part, the basis of Petitioner's challenge to the Decision in the Motion for Review." ECF No. 114 at 2-3. Thereafter, the Parties collectively "filed ten expert reports, offering competing takes on a causation theory . . . that the HPV and Hep. A vaccines can stimulate the production of autoantibodies that could be causal of autonomic disfunction, primarily manifesting as

[2] Tachycardia is "excessive rapidity in the action of the heart" and sinus tachycardia is "tachycardia originating in the sinus node." ECF. No. 114 at 1-2 n.1 (internal citations omitted). "Inappropriate sinus tachycardia, also called chronic nonparoxysmal sinus tachycardia, is an unusual condition that occurs in individuals without apparent heart disease or other cause for sinus tachycardia, such as hyperthyroidism or fever, and is generally . . . defined as a resting heart rate >100 beats per minute (with a mean heart rate>90 beats per minute over 24 hours) associated with highly symptomatic palpitations . . . ." *Id.*

[3] "POTS is a circulation disorder characterized by a group of symptoms (not including hypotension) that sometimes occur when a person assumes an upright position, including tachycardia, tremulousness, lightheadedness, sweating, and hyperventilation." ECF No. 109 at 26 (citing *Postural orthostatic tachycardia syndrome*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111236 (last visited July 14, 2022)).

orthostatic intolerance." ECF No. 109 at 2. Summaries of Petitioner's medical records and each Party's expert opinions are set forth in detail below.

On July 12, 2018, the Parties informed the Court that they were not engaged in settlement discussions and requested a hearing date. *See* ECF No. 72 at 4. That day, Special Master Sanders issued an Order providing that "[d]ue to the high volume of cases that are ready for entitlement hearings and the limited number of Special Masters, no additional hearings will be scheduled until further notice. Chambers will reach out to the parties when hearing dates become available." ECF No. 71. In March 2021, this case was reassigned to Chief Special Master Corcoran, who directed the Parties to conclude filing expert reports and briefings, and indicated that the matter would be resolved by a ruling on the record. *See* Docket Entry Order, dated March 23, 2021. The Chief Special Master issued his Decision on July 15, 2022. ECF No. 109.

A. Petitioner's Medical History

1. Pre-Vaccination Medical History

Petitioner was born on March 3, 1997. Pet'r's Ex. 2 at 1 (ECF No. 6-2). Petitioner claims that her health had been generally "stable" prior to receiving the Hep. A and HPV vaccinations at issue, and "the emergence of symptoms [did not occur until] after the August 4, 2015 and August 19, 2015 vaccinations." ECF No. 114 at 8-9. In issuing his decision the Chief Special Master reviewed the administrative record, including Petitioner's relevant medical history, and identified "three notable events" based on her pre-vaccination medical records:

> First, she saw a cardiologist in June 2008 for episodes of shortness of breath and difficulty breathing while swimming, but her symptoms were later attributed to asthma. Second, she underwent a head MRI on October 1, 2008, for occipital migraines, which showed evidence for sinusitis, but was otherwise normal. Finally, in March 2012 she was evaluated by an endocrinologist for autoimmune thyroid disease. At that time, she tested positive for antibodies relevant to the disease, but was not yet symptomatic, although she did report joint aches and ongoing abdominal complaints.

ECF No. 109 at 2 (citing Pet'r's Ex. 2 at 55-56, 58-61 (ECF No. 6-2); Pet'r's Ex. 15 at 1-2 (ECF No. 12-1)).

Petitioner contests the significance of each "notable event[]" cited by the Chief Special Master. First, Petitioner argues that, although the June 10, 2008, medical report suggests "episodes of shortness of breath and difficulty breathing while swimming" related to asthma, the "record shows *no* diagnosis or other reference to asthma or reactive airway disease." ECF No. 114 at 7 (citing Pet'r's Ex. 3 at 58-62 (ECF No. 6-3)) (emphasis in original). However, pursuant to the 2008 report, "[a]n electrocardiogram was preformed which . . . show[ed] sinus rhythm alternating with an atrial ectopic rhythm." Pet'r's Ex. 3 at 58 (ECF No. 6-3). While Petitioner's treating physician indicated this was "nothing of concern by itself[,]" he found Petitioner's "symptoms appear more compatible with reactive airway disease than the classic cardiac findings of syncope in a pool with relevant family history." *Id.* at 59. Second, Petitioner concedes she submitted to an MRI in October 2008, which was "normal, except for noting

evidence of sinusitis."[4] ECF No. 114 at 8. She suggests, however, that the MRI was intended to, and did in fact, rule out occipital migraine as cause for her eye pain, loss of vision, and nausea, thereby failing to render it "notable." *Id.* at 7-8; *see* Pet'r's Ex. 3 at 10 (ECF No. 6-3). Finally, Petitioner agrees that her "thyroid functioning was normal, despite the presence of antibodies indicative of autoimmune thyroid disease" in 2012. ECF No. 114 at 8. Specifically, she "presented to Riverview Medical Center on August 17, 2012[5] with a history of diarrhea, fever, nausea, abdominal pain, nasal discharge, fatigue, and cough . . . [and] had slightly positive tests for campylobacter jejuni and Coxsackie A and B viruses." *Id.* at 9; *see* Pet'r's Ex. 7 at 281-300 (ECF No. 6-9). These tests indicated "strong evidence of current or recent infection." Pet'r's Ex. 7 at 292-93 (ECF No. 6-9).

2. Post-Vaccination Hospitalizations

Petitioner received the Hep. A vaccine on August 4, 2015, and the first dose of the Gardasil HPV vaccine on August 19, 2015. Pet'r's Ex. 3 at 29 (ECF No. 6-3). On August 20, 2015, Petitioner began experiencing anxiety and hyperventilation, and sought treatment at Riverview Medical Center. Pet'r's Ex. 7 at 211-13 (ECF No. 6-9). There, Petitioner reported experiencing recent feelings of sadness, was planning to leave for college the next day, and, according to a Nurse's Note, that she "broke up with [her] boyfriend."[6] *Id.* at 224. The treating physician diagnosed her with an "anxiety reaction" and instructed her to follow up with a psychologist in one to two days. *Id.* at 229. The next day, Petitioner returned to the hospital by ambulance, again complaining of anxiety. *Id.* at 180-84. She appeared distressed to a degree "inappropriate for [her] age" and underwent a complete blood panel, metabolic panel, toxicology screen, and pregnancy test—each resulting in negative or noncontributory findings. *Id.* at 180-84, 187. She was ultimately discharged with a prescription for Ativan to take as needed for her diagnosed anxiety reaction. *Id.* at 189-90, 192.

On August 22, 2015, Petitioner returned to the hospital by ambulance. She appeared awake, anxious, and to experience "twitching" movements. Pet'r's Ex. 6 at 57, 72 (ECF No. 6-7). She transferred to Jersey Shore Hospital for further evaluation and heightened care. *Id.* at 57-58, 72. Petitioner reported experiencing "3 days of episodes of tonic-clonic jerking that last 20-40 minutes each and are associated with hyperventilation." *Id.*at 77. She also indicated this "[j]erking involves all 4 extremities. . . . [She] has never had episodes like this before. . . . [She] reports having a headache with mild sensitivity to light but states it is normal for her as she has a

[4] Petitioner's MRI radiology report references a history of occipital migraines, while otherwise finding "[n]ormal magnetic resonance imaging of the brain" with "nonspecific . . . evidence of left-sided maxillary sinus . . . ." Pet'r's Ex. 3-1 at 56-57 (ECF No. 6-3).

[5] Petitioner takes issue with Respondent's "incorrect reporting of dates, [which suggests] that Petitioner's symptoms predated her August 4, 2015 Hepatitis A and August 19, 2015 Gardasil vaccinations . . . ." ECF No. 114 at 8-9 n.6. Indeed, the correct date of Petitioner's visit is August 17, 2012, rather than August 17, 2015, as included in Respondent's briefing. Pet'r's Ex. 7 at 281-300 (ECF No. 6-9).

[6] Petitioner disputes that she had broken up with her boyfriend and argues the hospital record is incorrect on this point. However, resolution of this fact does not impact the resolution of this case.

h/o [history of] migraines." *Id.* The medical intake form does not reference Petitioner's hospital visits over the preceding three days—only that she visited the "ER . . . (not admitted) for MVA 3 months ago." *Id.* Petitioner received an initial diagnosis of "pseudoseizures"[7] while treating physicians continued to evaluate her. *Id.* at 38, 40-42, 80, 131.

Petitioner submitted to a video EEG on August 23-24, 2015, which was normal despite jerking episodes not accompanied by electrical discharge. *Id.* at 92; *see also id*. at 40 ("EEG has shown that [Petitioner] has not had any seizure-like activity."). Petitioner also underwent consultations for infectious diseases (Dr. Davis), neurological disorders (Dr. Sultan), and psychiatric conditions (Dr. Vincent), acknowledging her recent trip to Nicaragua and familial history of autoimmune issues, including a grandmother with myasthenia gravis. *Id.* at 33-42. Dr. Davis "observed the temporal association with [Petitioner's] receipt of the first HPV dose, and even wondered whether she may have had an adverse reaction, but felt that her symptoms would resolve with time." ECF No. 109 at 4 (citing Pet'r's Ex. 6 at 35 (ECF No. 6-7)). Dr. Sultan cited acute anxiety disorder, indicating Petitioner was unlikely experiencing "myoclonic seizure," while failing to rule out PANDAS[8] variant, underlying cardiac pathology, and reaction to the Gardasil vaccine. Pet'r's Ex. 6 at 38 (ECF No. 6-7). Dr. Vincent diagnosed Petitioner with panic attacks and advised her to seek therapy at college, although he did not rule out possible vaccine reaction or neurological issues. *Id.* at 42. The attending physician, Dr. Chin, also found Petitioner's "[c]ardiac evaluation [to be] normal, and [her symptoms] unlikely to be related to an underlying cardiac etiology." *Id.* at 130. On August 26, 2015, Dr. Topilow submitted a Vaccine Adverse Event Reporting System report highlighting Petitioner's "twitching" and "jerking" symptoms following the HPV vaccine administered on August 19, 2015. Pet'r's Ex. 3 at 37 (ECF No. 6-3). Petitioner's final diagnosis was "[a]nxiety based events not related to vaccine." Pet'r's Ex. 6 at 131 (ECF No. 6-7).

On September 2, 2015, Dr. Wells, a neurologist at NYU, further evaluated Petitioner. She described for him several episodes of "prolonged tachycardia" and "myoclonic jerking" initiating on August 20, 2015. Pet'r's Ex. 21 at 1-6 (ECF No. 28-1). Dr. Wells reviewed a video of an episode taken on Petitioner's mother's smartphone and was unable to determine if the "jerking" movements were involuntary. *Id.* at 4. Dr. Wells concluded that Petitioner "appears to be having episodes that are primarily anxiety based. They are unlikely to be seizures given the normal video EEG while having myoclonic episodes." *Id.* He surmised that the Gardasil vaccination is an unlikely cause for her symptoms and, rather, recommended that she visit a therapist for counseling. *Id.*

---

[7] "A pseudoseizure is 'an attack resembling an epileptic seizure but being a type of conversion disorder; it lacks the electroencephalographic characteristics of epilepsy and the patient may be able to stop it by an act of will.'" ECF No. 109 at 3 n.5 (citing *Pseudoseizure*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111236 (last visited July 14, 2022)).

[8] "'PANDAS' stands for Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus infections." ECF No. 109 at 4 n.6 (citing *Bains v. Sec'y of Health & Hum. Servs.*, No. 18-1212V, 2019 WL 4121084, at *1 (Fed. Cl. Spec. Mstr. July 26, 2019)).

On September 12, 2015, Petitioner went to the emergency room at Rhode Island Hospital complaining of "shaking, tremor episodes, . . . myoclonic jerks . . . [and] her joints beginning to 'lock up . . . .'" ECF No. 114 at 11 (citing Pet'r's Ex. 5 at 3-4 (ECF No. 6-6)). Petitioner's mother, who accompanied her to the hospital, informed physicians "that these reactions increase with loud noises[,] 'when she is startled and scared[,]' . . . [and are] exacerbated by stressful factors." Pet'r's Ex. 5 at 3-4 (ECF No. 6-6). The hospital administered an ECG, which was negative, and reviewed prior psychologist consultation records, which indicated anxiety may be causing her symptoms. *Id.* at 4, 15.

Five days later, on September 17, 2015, Petitioner was admitted to Riverview Medical Center "under observation status with intravenous Ativan on call for seizure-like activity." Pet'r's Ex. 7 at 90 (ECF No. 6-8). The results of her ECG were "normal" noting "normal sinus rhythm with sinus arrhythmia." *Id.* at 46. A subsequent neurology consultation suggested "[p]robable pseudoseizures." *Id.* at 67. The neurologist reported Petitioner's condition "[s]eems to be some stress related psycho-somatization[,] somatization . . . [or] anxiety associated panic . . . from ongoing stress" rather than "post-vaccine complication[s] causing seizures." *Id.* He advised "further psych evaluation and treatment for . . . psycho-somatization or psych disorder" if Petitioner's evaluation for seizures continued to yield negative results. *Id.*; *see* Pet'r's Ex. 9 at 25 (ECF No. 7-1) (describing "negative imaging, negative vEEG, and negative infectious workup").

Petitioner transferred to New York Hospital on September 18, 2015, for further evaluation. There, her laboratory testing, autoimmune testing, and EKG were normal. Pet'r's Ex. 7 at 77-80, 130 (ECF No. 6-8); Pet'r's Ex. 9 at 62 (ECF No. 7-1). A two-day video EEG captured a "shaking episode" following a BP reading of 79/52, "but there was no evidence of seizure activity on the EEG. The vEEG findings, along with the long duration of most of her episodes (20-40 minutes), lack of tongue biting and incontinence, and maintenance of awareness/verbal communication point towards a psychogenic non-epileptic seizure (pseudoseizure)." Pet'r's Ex. 9 at 62, 64, 70 (ECF No. 7-1) ("One of her typical spells was captured, characterized by jerking and shaking movements with no EEG correlation[.] [These] findings indicate nonepileptic events."). Accordingly, Petitioner was "cleared from neurologic perspective [and] discharged home with follow up." *Id.* at 66. A pediatric resident reviewed Petitioner's concerns regarding the onset of symptoms following receipt of the HPV vaccination, commenting that "[the] literature largely disclaims an association between the vaccination and neurologic disease . . . [and] most likely this is not the underlying etiology." *Id.* at 58. Additionally, a neurology attending noted that Petitioner's condition is "compelling for psychogenic spells" and encouraged "therapeutic intervention" to address "an underlying subconscious stressor causing the events." *Id.* at 70-71. Petitioner was discharged on September 22, 2015. *Id.* at 71.

3. 2015 Medical Evaluations

On October 2, 2015, Petitioner saw Dr. Lefkowitz, a cardiologist. Pet'r's Ex. 3 at 92 (ECF No. 6-4). Dr. Lefkowitz reviewed Petitioner's medical history, acknowledging that her prior "video EEG . . . showed no seizure activity during myoclonic activity" and noting Petitioner's record of IgA deficiency, antithyroid antibodies, and anti-insulin antibodies. *Id.* Dr. Lefkowitz conducted a "sit-stand" test, which revealed an increase in heart rate, from 62 bpm to

99 bpm, but no corresponding increase in blood pressure. *Id.* at 93. He also administered a 24 Hour Holter Report, which indicated Petitioner's "maximum heart rate was 150 bpm . . . during sinus tachycardia" and she experienced "46 runs of supraventricular tachycardia/paroxysmal atrial tachycardia." Pet'r's Ex. 12 at 12 (ECF No. 7-4). After completing his examination, Dr. Lefkowitz provided the following findings:

> Problem #1: Shy-Drager syndrome[9] (ICD-333.0) (ICD10-G90.3) The patient appears to have developed generalized autonomic dysfunction either on the basis of a reaction to her various vaccines that occurred at the same time, or possibly on the basis of a viral syndrome that she acquired while traveling through the jungles of Central America. Her MRI was apparently difficult to interpret in terms of demyelination, and should be reevaluated. She does respond to fluids and hydration, and to salt intake. This syndrome whether a self-limited immune response to the vaccine, i.e. a form fruste of multiple sclerosis, or a viral response which was stimulated immune reaction such as is seen in Guillain-Barre syndrome, with both ultimately be self-limited. They would respond to fluid intake, and a slow increase in exercise tolerance. I believe that this will be self-limited. I do believe she should hydrate aggressively with G2 or Smart water, and I believe that we have shown that the tonic-clonic movements are unrelated to seizure activity based upon the EEG. She also had no loss of urine or bowel. I think the final answer regarding the tonic-clonic movements will depend on either a different interpretation of the MRI, or perhaps a repeat MRI.
>
> Problem #2: Palpitations, recurrent (ICD-785.1) (ICD10-R00.2) The patient's Holter is consistent with inappropriate sinus tachycardia. This can be seen in the setting of autonomic dysfunction. While I believe the autonomic dysfunction is on the basis of either vaccines, or viral exposure, this should be a way to address whether or not the antibody to insulin can cause autonomic dysfunction in the setting of a diabetic-like state. I doubt that this is the case. Thyroid function testing was unremarkable, therefore she is not hyperthyroid despite the presence of antibodies. The palpitations and inappropriate sinus tachycardia should respond to fluids and rest, but I'm going to prescribe low-dose metoprolol to take when they become very uncomfortable. Eventually I suspect she will no longer needs to beta-blockade over time. Fortunately, there is no evidence of malignant arrhythmia, or an arrhythmia that would need to be ablated.
>
> Problem #3: Chest pain, precordial (ICD-786.51) (ICD10-R07.2) The chest pain is a little bit more difficult to explain. The patient has a normal EKG, and normal left ventricular function. Her right side is not dilated, and pulmonary artery systolic pressures are normal, so I don't think it is likely that she had a pulmonary embolus that would cause her to have pain. Her oxygen saturation is normal as well. . . . Whether or not the chest pain is secondary to pericarditis, is unclear. While she has evidence of concordance of the

[9] "Shy-Drager syndrome is another term for multiple system atrophy ("MSA")—'a rare, degenerative neurological disorder affecting your body's involuntary (autonomic) functions, including blood pressure, breathing, bladder function and motor control.' It shares many Parkinson's disease-like symptoms, such as slow movement, rigid muscles, and poor balance." ECF No. 109 at 7 (quoting ECF No. 106 at 8 n.6).

> pericardium, there is no evidence of pericarditis on her EKG, and sedimentation rate and CRP are both normal. If she had pericarditis, she had it in the past in my opinion. . . .
>
> Problem #4: Symptom, convulsions NOS (ICD-780.39) (ICD10- R56.9) As outlined above, there is no correlation with seizure activity on EEG. This may be some reaction of the central nervous system 20 over the median stimulant this. I await the repeat MRI interpretation, and possibly a repeat neurology evaluation.

Pet'r's Ex. 3 at 93-94 (ECF No. 6-4).

On October 13, 2015, Petitioner saw Dr. Nash, an infectious disease and pulmonary specialist. Dr. Nash found the psychogenic seizure diagnosis incompatible with her clinical presentation and personality/behavior presentation. Pet'r's Ex. 4 at 3 (ECF No. 6-5). Specifically, Dr. Nash commented that "the multiplicity of [Petitioner's] symptoms (twitching, shortness of breath, fever, chest pain) is well beyond what one would expect from straightforward panic/anxiety reaction." *Id.* He suggested "[t]he timing of her symptoms and the immunizations may represent coincidence or perhaps that she had a degree of autoimmune encephalopathy provoked by immunizations in a susceptible patient with an autoimmune predisposition." *Id.* Alternatively, he considered whether her symptoms could be caused by "an infection that she picked up while in Nicaragua." He concluded that the infections "that would cause CNS symptoms typically are associated with eosinophilia and an abnormal MRI." *Id.* He also opined that "[s]he has minor orthostatic changes which are not consistent with POTS or significant autonomic instability." *Id.* Dr. Nash recommended further testing for inflammation and infection, autoimmune encephalitis, and cerebral spinal fluid evaluation for seizure-like activities. *Id.* Such testing yielded unremarkable results that did not corroborate the presence of an autoimmune condition or autonomic dysfunction. *See Id.* at 7 (MRI results showing white matter disease "associated with migraine headaches, vasculopathy, toxins, prior trauma, or prior inflammatory diseases, all of which can give a similar appearance.").

On November 18, 2015, Dr. Kaufmann and Dr. Palma—both neurology specialists in dysautonomia—submitted Petitioner to neurological, autonomic, and paraneoplastic autoimmune testing. Pet'r's Ex. 18 at 1-3 (ECF No. 18-1). Such testing included a "tilt table" test,[10] during which Petitioner experienced "an episode of bilateral convulsive movements with no loss of consciousness accompanied by palpitations, sinus tachycardia, and shortness of breath." *Id.* at 3. Petitioner's blood pressure rose from 108 to 136 after 11 minutes of head-tilt, and her plasma concentration of norepinephrine increased from 252 to 619 when tilted. *Id.* The results of the autoimmune panel revealed no abnormal antibodies, and Petitioner "preserved cardiovascular autonomic reflexes with no evidence of orthostatic hypotension." *Id.* Further, her testing indicated that Petitioner's "observed episode, as well as her previous episodes[,] are consistent with non-epileptic seizures." *Id.* Testing did not establish that Petitioner suffered from POTS.

[10] "The standard tilt table test entails the patient remaining in a supine position on an adjustable table for twenty minutes, followed by ten minutes tilted upright, with the heart rate and blood pressure measured minute by minute, to detect changes as position is altered." ECF No. 109 at 7 (citing *Yalacki v. Sec'y of Health & Hum. Servs.*, No. 14-278V, 2019 WL 1061429, at *40 n.10 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *mot. for review den'd*, 146 Fed. Cl. 80 (2019)). This test is "often considered the 'gold standard' in diagnosing POTS." *Id.*

Dr. Kaufmann and Dr. Palma concluded that "[t]he marked increase in circulating epinephrine (from 17 to 160 pg/ml) . . . typically occurs in panic disorders." *Id.*; *see also* ECF No. 109 at 8 n.11 ("Epinephrine is a hormone released by the adrenal glands in response to stress"). The neurologists explained to Petitioner "how repeated panic attacks result in reuptake of epinephrine by sympathetic nerves, and as result, episodes of sympathetic activation, like exercise, may produce excessive epinephrine release and panic-like symptoms." Pet'r's Ex. 18 at 3 (ECF No. 18-1). Accordingly, they suggested techniques to improve symptoms, which included "cognitive behavioral therapy, biofeedback[,] . . . mindfulness, yoga[,] breathing . . . [and] [b]eta-blockade (e.g., Toprol)[,] [which] is successful for managing stage fright and other stressful situations . . . ." *Id.*

Later that month, Petitioner had a follow-up appointment with Dr. Lefkowitz, where she reported feeling "less orthostatic" and "much better overall." Pet'r's Ex. 3 at 97 (ECF No. 6-4). She also stated that "[s]he no longer has palpitations, dizziness, or tremors." *Id.* Dr. Lefkowitz found her "asymptomatic" with respect to shy-drager syndrome, which had "[c]linically much improved." *Id.* at 98. He also suggested "whatever the immunoresponse that stimulated [her convulsions] resolved nearly completely." *Id.*

Despite these improvements, Petitioner was admitted to the emergency department at Robert Wood Johnson University Hospital on December 5, 2015, exhibiting "convulsions." Pet'r's Ex. 11 at 2 (ECF No. 7-3). The intake report indicates that, according to Petitioner's mother, she "has had pseudo-seizures since August when she received [her] first round of Gaurdasil [sic]." *Id.* The initial assessment provided that Petitioner "is a 18 year old with IgA deficiency presenting after sudden loss of consciousness and left lower extremities weakness with likely etiology autonomic dysfunction secondary to Gardasil vaccination." *Id.* at 72. While her laboratory tests were normal, an EKG showed sinus tachycardia. *Id.* at 8-10.

A few days later, Petitioner was admitted to the Monmouth Medical Center Emergency Department, complaining of "generalized body aches . . . with mild sore throat" and "occasional chest pressure." Pet'r's Ex. 3 at 88 (ECF No. 6-4). The intake report now noted "a history of POTS" and "extensive evaluation for episodes of tachycardia, leg weakness and pseudoseizures following her initial immunization of Gardasil several years ago." *Id.* at 88. While admitted, Petitioner experienced an episode of chest pain and tachycardia; however, the ECG, EKG, cardiac monitor, and oxygenation levels remained normal. *Id.* at 91. Dr. Snyder subsequently ordered her discharge and "encouraged strongly the child start[] beta blockers[11] for prevention." *Id.*

4. 2016-2020 Medical Evaluations and Treatment

In February 2016, Dr. Lefkowitz submitted Petitioner to Zio Patch Electrocardiography Monitoring for two weeks. Pet'r's Ex. 12 at 4 (ECF No. 7-4). The results showed a maximum heart rate of "203 bpm which occurred during a 13 beat or 6.4 second run of ventricular

[11] "Beta blockers, also known as beta-adrenergic blocking agents, can be recommended for reducing anxiety, because they inhibit the effects of adrenaline." ECF No. 109 at 9 n.13 (citing *Beta Blockers*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/beta-blockers/art-20044522 (last accessed on June 30, 2022)).

tachycardia" as well as instances of premature atrial and ventricular contractions and paroxysmal atrial tachycardia. *Id.* "There was no supraventricular tachycardia" and "no atrial fibrillation or atrial flutter." *Id.* Nevertheless, on June 26, 2016, Dr. Lefkowitz provided Petitioner with a letter that indicated he "diagnosed her with an autonomic disfunction due to the HPV vaccine . . . . [and,] [a]s a result of this, she cannot complete the course of the HPV vaccine." *Id.* at 3. The letter also cleared Petitioner to return to college "without restriction." *Id.*

In April 2016, Petitioner went to Riverview Medical Center complaining of nausea, vomiting, and abdominal pain. Pet'r's Ex. 13 at 10 (ECF No. 9-1). Her medical history, as reported, included POTS disease and a history "of being immunocompromised secondary to the Gardasil vaccination." *Id.* She was discharged following a physical evaluation, which did not yield abnormal results. *Id.*

In September 2016, Petitioner arrived at Roger Williams Medical Center exhibiting body tremors and hyperventilation. Pet'r's Ex. 14 at 2 (ECF No. 10-1). While her physical evaluation was normal, an EKG showed sinus tachycardia. *Id.* In November, Petitioner returned to the emergency room "for evaluation of near syncopal episode and tachycardia onset . . . secondary to missing a dose of Metoprolol . . . ." Pet'r's Ex. 29 at 32 (ECF No. 56-1). She was "informed that [she] may have pre-hypertension and hypertension based on a blood pressure reading" and was discharged after her condition improved. *Id.* at 34.

In April 2017, Petitioner returned to the emergency room complaining of possible tachycardia and seizure. *Id.* at 60. Her blood pressure was documented as high, in the 150s, and her "blood pressure was fluctuating." *Id.* Treating physicians reiterated that she "may have pre-hypertension and hypertension based on a blood pressure reading" and recommended following up with her primary care provider following discharge. *Id.* at 63.

In October 2017, Dr. Lefkowitz performed an echocardiogram in reaction to Petitioner's claim of "chest pain." Dr. Lefkowitz also recommended an MRI to evaluate an intermittent mass near her heart. Pet'r's Ex. 33 at 26. Dr. Lefkowitz identified myxoma[12] as possible explanation for her presentation. Pet'r's Ex. 33 at 27 (ECF No. 60-1). He also indicated Petitioner's "blood pressure goes up and her heart rate goes down as opposed to the opposite which would be more consistent with potts [sic] syndrome." *Id.* at 26. Testing suggested Petitioner's symptoms were "consistent with massive activation" and her pulse and blood pressure were "consistent with orthostasis." *Id.* Additionally, Petitioner's vivid dreams, anemia, abdominal pain, and nausea "could be associated with porphyria." *Id.*

Petitioner's medical records indicate that she did not seek medical attention again until March 28, 2019, when she presented to North Attleboro Urgent Care with complaints of abdominal pain. Pet'r's Ex. 36 at 4 (ECF No. 77-1). A CT scan revealed "no acute intra-abdominal or pelvic abnormality" and was otherwise negative, except for "[l]arge fecal loading of the entire colon." *Id.* at 25. The following year, in March 2020, Petitioner consulted Dr.

[12] "Myxoma is 'a benign tumor composed of primitive connective tissue cells and stroma resembling mesenchyme.'" ECF No. 109 at 10 n.14 (citing *Myxoma*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111236 (last visited July 14, 2022)).

Vargas, a neurologist, regarding "an abnormal MRI and cognitive complaints." Pet'r's Ex. 38 at 12 (ECF No. 77-3). Dr. Vargas reported that "[s]ince our last visit, [Petitioner] had labs which were WNL [within normal limits]." *Id.* at 12. She also indicated that Petitioner's MRI "was stable in terms of lesions but did show a tiny 3 mm hypoenhancing focus related to the pituitary gland." *Id.* at 12.

In 2016 and 2020, Petitioner submitted blood samples for further antibody laboratory testing. CellTrend GmbH, a laboratory in Germany, tested Petitioner for adrenergic and muscarinic antibodies[13] in February 2016, two of which were found to be positive. Pet'r's Ex. 16 at 1-2 (ECF No. 12-2). Further, results received in August 2016 indicated high levels of GAD antibodies, IA-2 antibodies, Zinc Transporter 8 antibodies, and antinuclear antibodies (ANA). Pet'r's Ex. 15 at 11 (ECF No. 12-1). Four years later, in March 2020, Petitioner was retested by CellTrend GmbH.[14] The results showed positive levels of Anti alpha-1 adrenergic antibodies measuring 19.4 Units/ml, Pet'r's Ex. 37 at 1 (ECF No. 77-2), which exceeded the 2016 measurement of 7.1 Units/ml.1, Pet'r's Ex. 16 at 1 (ECF No. 12-2). Petitioner's results were otherwise negative, except for one at risk value for Anti ETAR antibodies, which measured at 12.1 Units/ml. Pet'r's Ex. 37 at 1 (ECF No. 77-2). The following month, Petitioner underwent testing for neuromuscular antibodies at Washington University School of Medicine. The results were negative, except one "borderline" positive reading for IgM vs Neurofascin-155, which "has been associated with chronic and acute neuropathies with distal weakness, sensory loss and tremor." Pet'r's Ex. 40 at 1 (ECF No. 77-5).

B. Expert Opinions

Petitioner relies upon expert opinions to show that her HPV vaccination caused her claimed injuries, and Respondent relies upon expert opinions to show that Petitioner's HPV vaccination did not cause her claimed injuries. *See* ECF No. 41 at 10-11, ECF No. 43 at 1. Ultimately, the Chief Special Master reviewed ten expert reports from four medical experts. *See* Ex. 28 (ECF No. 49-1), Ex. A (ECF No. 63-1), Ex. C (ECF No. 65-1), Ex. 35 (ECF No. 68-1), Ex. E (ECF No. 70-1), Ex. 49 (ECF No. 92-1), Ex. 60 (ECF No. 93-1), Ex. F (ECF No. 99-1), Ex. G (ECF No. 99-14), and Ex. 63 (ECF No. 100-1).

1. Dr. Steinman's First Report

Petitioner's initial expert report is by Dr. Lawrence Steinman. *See* Pet'r's Ex. 28 (ECF No. 49-1). Dr. Steinman is a neurologist who has practiced adult and pediatric neurology for 37 years. *Id.* at 1. He is also Professor of Neurology at Stanford University. *Id.*

---

[13] Petitioner filed medical literature indicating a possible connection between positive adrenergic and muscarinic antibodies and patients diagnosed with POTS. *See* Pet'r's Ex. 23 (ECF No. 42-5). The report further suggested "[t]he temporal relationship of . . . symptoms to HPV vaccination and the detection of numerous relevant antibodies raise[s] the hypothesis of an autoimmune basis for [the] symptoms." *Id.*

[14] Petitioner indicated that such testing was secured to support an autoimmune etiology evidenced by elevated norepinephrine levels. ECF No. 108 at 6-7.

Dr. Steinman concluded "by a preponderance of evidence" that "the Hepatitis A vaccine received by J.S. on August 4, 2015, and the Gardasil vaccine received by J.S. on August 19, 2015" caused Petitioner to develop an "autoimmune dysautonomia with inappropriate tachycardia." *Id.* at 18. Dr. Steinman's theory is based "on the concept of molecular mimicry." *Id.* at 6. According to his theory, "a vaccine can trigger a cross-reactive autoimmune response directed to self" when the vaccine contains an "effective molecular mimic." *Id.* at 6-9. An effective molecular mimic is one that is "capable of inducing clinical paralysis when injected into an experimental animal of the right genetic background," a standard Dr. Steinman based on two peer reviewed papers. *Id.* at 9; *see* A. Guatam, *A Viral Peptide with Limited Homology to a Self Peptide Can Induce Clinical Signs of Experimental Autoimmune Encephalomyelitis*, 161 J. Imunol. 60 (1998), filed as Ex. 28, Ref. 16 on Oct. 29, 2017 (ECF No. 48-7); A. Guatam, *Minimum Structural Requirements for Peptide Presentation by Major Histocompatibility Complex Class II Molecules: Implications in Induction of Autoimmunity*, 91 Proc. Natl. Acad. Sci. USA 767 (1994), filed as Ex. 28, Ref. 17 on Oct. 29, 2017 (ECF No. 48-8). According to these papers, paralysis was induced when vaccine components shared "a stretch of 12 amino acids where at least 5 are identical" with the patient's adrenergic receptor. Pet'r's Ex. 28 at 7, 9-10 (ECF No. 49-1).

Dr. Steinman found that Petitioner has alpha 1 adrenergic receptor antibodies. *Id.* at 15 (discussing Ex. 16 (ECF No. 12-2)). The presence of these antibodies had been "associated with POTS, dysautonomia and inappropriate tachycardia, which are mainly autoimmune to adrenergic receptors." *Id.* at 6 (citing H. Li, *Autoimmune Basis for Postural Tachycardia Syndrome*, J. Am. Heart Assoc. 1 (2014) (filed as Ex. 28, Ref. 12 on October 29, 2017 (ECF No. 48-3)). Theorizing that Petitioner's Gardasil or Hep. A vaccines triggered her antibodies, Dr. Steinman looked at the components of the vaccines and "performed BLAST searches at the website of the National Library of Medicine to search for relevant structural homologies." *Id.* at 7-8. Dr. Steinman "found some highly relevant molecular mimics in both the hepatitis A vaccine and in the Gardasil vaccine." *Id.* at 8. When Dr. Steinman compared the Gardasil vaccine to the alpha 1 adrenergic receptor, he found one sequence of 13 amino acids that contained 7 identical amino acids, and another sequence of 12 amino acids that contained 6 identical amino acids. *Id.* at 11-12. And when he compared the Hep. A vaccine to the alpha 1 adrenergic receptor, he found one sequence of 10 amino acids that contained 7 identical amino acids, another sequence of 8 amino acids that contained 5 identical amino acids, and a sequence of 9 amino acids that contained 5 identical amino acids. *Id.* at 13-14.[15] Due to the similarities, Dr. Steinman concluded that "the components of the Gardasil vaccine and the Hepatitis A vaccine have sufficient identity to human adrenergic receptor" to have triggered Petitioner's antibodies. *Id.* at 14-15. Dr. Steinman opined they did so, and he believed that their existence indicated that the vaccines caused Petitioner's autoimmune dysautonomia with inappropriate tachycardia. *Id.* at 18.

[15] Dr. Steinman acknowledged that the "adrenergic receptor sequences elicited by Gardasil vaccine and by the Hepatitis A vaccine are different," but was not concerned because due to intramolecular epitope spreading, "once tolerance is broken to one component of an antigen the immune response can spread to other regions of the molecule." Pet'r's Ex. 28 at 15 (ECF No. 49-1).

Dr. Steinman asserted that his theory is consistent with Petitioner's symptoms. As he pointed out, the rapid onset of adverse reactions, including syncope, has been reported following Gardasil vaccination. *Id.* Also, Petitioner's heart began racing "within a day of the Gardasil vaccine," and "15 to 16 days after the Hepatitis A vaccine," a response Dr. Steinman found "totally consistent with timing of adverse events reported in the package insert for Gardasil, and from the velocity of the recall response described in the 2012 IOM report." *Id.*

Dr. Steinman also contended that his theory and analysis satisfy the *Althen* test. *Id.* at 19. He claimed causation is established by his theory of molecular mimicry, which shows that the Gardasil and Hep. A vaccines elicited immunity to adrenergic receptors associated with dysautonomia and inappropriate tachycardia. *Id.* He then observed that his theory proved the vaccination was the reason for Petitioner's injury by demonstrating that the Gardasil vaccine antigens were sufficient to trigger a neuroinflammatory response when injected into Petitioner, resulting in an immune response which triggered a post-vaccine antibody mediated attack on the alpha 1 adrenergic receptor. *Id.* He also noted that a proximate temporal relationship between vaccination and injury was fulfilled by the onset of "heart racing" in the day or days after the Gardasil vaccine and 15 to 16 days after the Hep. A vaccine. *Id.*

2. Dr. MacGinnitie's First Report

Respondent provided a competing opinion by Andrew MacGinnitie, M.D., Ph.D. *See* Resp't's Ex. A (ECF No. 63-1). Dr. MacGinnitie is an Allergist/Immunologist who has practiced for 16 years and is currently Attending Physician and Clinical Director for the Division of Immunology at Boston Children's Hospital overseeing clinical operations for Allergy/Immunology, Rheumatology and Dermatology. *Id.* at 1. He is also Associate Professor of Pediatrics at Harvard Medical School. *Id.* Dr. MacGinnitie found "to a reasonable degree of medical certainty" that "it is extremely unlikely that J.S.'s symptoms are due to an immune reaction triggered by vaccination." *Id.* at 9. Dr. MacGinnitie based his conclusion on the implausibility of Dr. Steinman's theory of molecular mimicry. *Id.* at 4.

According to Dr. MacGinnitie, Dr. Steinman's theory of molecular mimicry has significant flaws regarding causation. First, according to Dr. MacGinnitie, Dr. Steinman's theory gives "too much credence to the presence of anti-adrenergic receptor antibodies, which are frequently present in normal controls." *Id.* at 4. Second, Dr. MacGinnitie believed that Dr. Steinman "rel[ied] on an outdated view of molecular mimicry." *Id.* Finally, Dr. MacGinnitie believed that Dr. Steinman "ignore[d] data that POTS is not, in fact, an autoimmune condition and that extensive epidemiologic data shows [sic] that Gardasil (HPV) and VAQTA (Hep A) vaccines are not associated with autoimmunity." *Id.*

a) POTS and Autoimmunity

Dr. MacGinnitie found that there is "little evidence and no consensus that POTS/dysautonomia is an autoimmune disease." *Id.* at 4. He observed that Dr. Steinman "ignores data that POTS is not, in fact, an autoimmune condition and that extensive epidemiologic data shows that Gardasil (HPV) and VAQTA (Hep A) vaccines are not associated with autoimmunity." *Id.* He also pointed to four studies that indicate "no relationship between HPV or Hep A/VAQTA vaccination and autoimmune disease." *Id.* at 8-9.

Dr. MacGinnitie admitted that Dr. Steinman cited the Li article in support of his theory that "POTS, dysautonomia and inappropriate tachycardia, which are mainly autoimmune to adrenergic components." *Id.* at 4. However, he pointed out that the study was "small" and that reviewers took issue with it. *Id.* He also observed that the study was not "a relevant model of human disease" because it "uses a completely different methodology in which antibodies (IgG) from patients and controls are added to a culture of rat cremaster arterioles." *Id.* 5-6.

b) CellTrend Assay

Dr. MacGinnitie observed that the Loebel article indicated "serious issues" with Petitioner's reliance on her CellTrend assay, which showed that she has alpha 1 adrenergic receptor antibodies. *Id.* at 5; *see* M. Loebel, *Antibodies to β Adrenergic and Muscarinic Cholinergic Receptors in Patients with Chronic Fatigue Syndrome*, 52 Brain, Behavior, and Immunity 32 (2015) (filed as Ex. A, Tab 7 on Feb. 7, 2018 (ECF No. 63-8)). Dr. MacGinnitie himself took issue with the assay because it "is not approved by the Food and Drug Administration ('FDA')," because "J.S.'s [reference] value was 7.3, barely above the cited upper range of normal (7.0) [in the assay] and . . . a value that is frequently seen in normal controls," and because a "more extensive panel of autoantibodies associated with dysautonomia was completely negative." Resp't's Ex. A at 5-6 (ECF No. 63-1) (citing Ex. 18 (ECF No. 18-1)).

Not only was Petitioner's value only slightly above the upper range, Dr. MacGinnitie opined that because five percent of normal individuals will have values outside the normal range, Petitioner's value "[wa]s likely not indicative of elevated levels, but within the range of normal variation." *Id*. at 5. Dr. MacGinnitie also distinguished the Loebel article because it was limited to patients with Chronic Fatigue Syndrome and provided no data on POTS or autonomic dysfunction. *Id.*

c) Mouse Model

Dr. MacGinnitie took issue with Dr. Steinman's reliance on the Guatam articles, which indicated that a vaccine with a stretch of 12 amino acids where at least 5 are identical with a patient's adrenergic receptor would cause humans to experience a cross-reactive autoimmune response directed to self. *Id.* at 6. Dr. MacGinnitie believes the references are of "at best marginal" significance because they rely on a mouse model, and there are "multiple examples of data in animals failing to translate into human disease." *Id.* Additionally, the mouse model used Complete Freund's Adjuvant, "a mix of mycobacterial proteins and mineral oil" that is "so powerful that it is not suitable for use in human use," whereas "[w]hile Gardasil and VAQTA use an adjuvant, it is aluminum, which is relatively weak and well tolerated." *Id.* at 6-7. The mouse model was also "of demyelination," which is "the basis of multiple sclerosis and related illnesses in humans" but not the basis of dysautonomia and POTS. *Id.* at 6.

3. Dr. Bingham's First Report

Respondent also filed a report by Dr. Peter M. Bingham. *See* Resp't's Ex. C (ECF No. 65-1). Dr. Bingham is a Pediatric Neurologist and clinical researcher with 25 years' post-residency experience in general child neurology. *Id.* at 1. Dr. Bingham concluded that it is "more likely than not" that Petitioner "did not suffer her symptoms . . . as a result of Gardasil

vaccination." *Id.* at 6.[16] Dr. Bingham based his theory on the lack of epidemiological evidence associating Gardasil and POTS in the "considerable discussion in the literature, case reports, [and] case series, regarding a potential link." *Id.*

Dr. Bingham characterized Petitioner's symptoms and positive antibody findings as "non-specific" and that "in many cases, individuals without any neurological disease may harbor these antibodies." *Id.* at 6-8. Moreover, "[n]ot all patients with POTS harbor these antibodies." *Id.* Because not all POTS patients have the adrenergic antibodies and it is not known how many people without POTS have the antibodies, Dr. Bingham concludes that the presence of the antibodies does not prove that Petitioner had an autoimmune disease.

He also opined that Dr. Steinman's opinion does not satisfy "the standards for causal attribution set by the Institute of Medicine regarding adverse effects of medicine" because it requires "a number of assumptions." *Id.* at 6.[17] For example, Dr. Bingham observed that there was a "relatively long period of latency before induction of the autoimmune response that [Dr. Steinman] and his colleagues elicited in mice." *Id.* at 7.

Based on his review, Dr. Bingham concluded if Petitioner had POTS, it was more likely than not that she did not develop it because of her Gardasil vaccination.

4. Dr. Steinman's Second Report

Petitioner responded to Respondent's experts with another report by Dr. Steinman. *See* Pet'r's Ex. 35 (ECF No. 68-1). After reading Respondent's reports, Dr. Steinman's "conclusions in this matter are unchanged." *Id.* at 20. Dr. Steinman acknowledged that Dr. MacGinnitie was correct that "immunity to nervous system antigens like myelin is rather widespread in normals." *Id.* at 3. However, he reiterated that "many diseases that are adjudicated in this court do not have a finally universally agreed mechanism of pathogenesis. Many disease entities have multiple mechanisms of pathogenesis. The Petitioner is asked to compose a theory. I base my theory in this case and in all others on the peer-reviewed literature." *Id.* at 10. He emphasized that his role "is not to provide a massive theory that proves how autoimmune disease is caused at a level of certainty," but rather "to provide a theory on how Petitioner's disease could be caused, based on solid peer reviewed publications." *Id.* at 18. Dr. Steinman then responded to Respondent's reports.

a) Dr. MacGinnitie

(1) POTS and Autoimmunity

[16] Dr. Bingham disagreed with Dr. Steinman that Petitioner had developed POTS because she did not demonstrate its core symptoms, "chronic, recurrent, orthostatic intolerance." Resp't's Ex. C at 5 (ECF No. 65-1).

[17] Dr. Bingham seemingly proposed that the Court rely on a test similar to the standards outlined in the Institute of Medicine report on Adverse Effects of Vaccinations rather than the *Althen* test, whose criteria he claimed are "considerably less stringent." Resp't's Ex. C at 8 (ECF No. 65-1).

Dr. Steinman emphasized that the Li article and two supplemental reports "discuss autoantibodies in POTS." *Id.* at 10; *see* Ex. 18; M. Thieben, *Postural Orthostatic Tachycardia Syndrome: The Mayo Clinic Experience*, 82 Mayo Clin. Proc. 308 (2007), filed as Ex. 35, Ref. 1 on Apr. 19, 2018 (ECF No. 68-2); X. Wang, *Autoimmunoreactive IgGs from Patients with Postural Orthostatic Tachycardia Syndrome*, 6 Proteomics Clin. Appl. 615 (2012), filed as Ex. 35, Ref. 2 on Apr. 19, 2018 (ECF No. 68-3). Dr. Steinman observed that Dr. MacGinnitie's statement that Dr. Steinman "ignores data that POTS is not, in fact, an autoimmune condition and that extensive epidemiologic data shows that Gardasil (HPV) and VAQTA (Hep A) vaccines are not associated with autoimmunity" is contradictory because "he states that POTS is not an autoimmune disease, and then he cites four references stating that the vaccines in Petitioner's theory are not associated with autoimmunity." Pet'r's Ex. 35 at 8 (ECF No. 68-1). Dr. Steinman reviewed Dr. MacGinnitie's four references and noted that they did not search for POTS specifically, and so "in no way rule out an association between POTS and the vaccines in question." *Id.*

Dr. Steinman took issue with Dr. MacGinnitie's portrayal of his words "POTS, dysautonomia and inappropriate tachycardia, which are mainly autoimmune to adrenergic components," stating the quotation was only partial and inaccurately portrayed him as qualifying his autoimmune theory to "all POTS patients." *Id.* at 10-11. Dr. Steinman then quoted the full passage which clarified that his opinion explained increased standing plasma norepinephrine and excessive tachycardia in "many POTS patients." *Id.* Dr. Steinman defended his use of the Li article and claimed that it "is a valid assay to measure anti-adrenergic antibodies." *Id.* at 15.

(2) CellTrend Assay

Dr. Steinman disagreed that the Loebel article indicates "serious issues" with the CellTrend assay and requested that Respondent explain what this assertion meant. *Id.* at 12-14. He then responded to Dr. MacGinnitie's comments about the FDA by explaining that lab testing "is not necessarily ever 'approved by the FDA.'" *Id.* at 13. He responded to Dr. MacGinnitie's comments about Petitioner's barely elevated antibody levels by saying "'above the cited upper range of normal', means EXACTLY that." *Id.* at 14. He also disagreed with Dr. MacGinnitie's description of Exhibit 18 as "a more extensive panel of autoantibodies," saying "it is simply a different panel and did NOT include anti-adrenergic antibodies." *Id.* at 12.

Dr. Steinman emphasized that the negative panel of antibodies Dr. MacGinnitie referred to, the Paraneoplastic assay, Exhibit 18, did not measure anti-adrenergic antibodies, and that Petitioner's CellTrend assay showed high levels of M4 antibodies. *Id.* at 12, 15. While Dr. Steinman admitted that "[t]he significance of antibodies to M4 in POTS is unknown," he emphasized that research indicates "patients with 'idiopathic' orthostatic hypotension (OH) have a strong association with activating autoantibodies." *Id.*

(3) Mouse Model

Dr. Steinman responded to Dr. MacGinnitie's critiques of the mouse model by explaining he relied on "a standard model of autoimmune disease – EAE – to support Petitioner's theory" because he did not have an "animal model of autoimmune POTS." *Id.* at 16. Dr. Steinman also cited a new report where researchers caused paralysis by "passively transferr[ing] T cells that

cross-reacted with myelin basic protein and HPV." *Id.* at 17; *see* R. Ufret-Vincenty, *In Vivo Survival of Viral Antigen-Specific T Cells that Induce Experimental Autoimmune Encephalomyelitis*, 188 J. Experimental Medicine 1725 (1998), filed as Ex. 35, Ref. 5 on Apr. 19, 2018 (ECF No. 68-6). The report concluded that "mimicry between a virus and myelin basic protein can lead to clinical paralysis." Pet'r's Ex. 35 at 17 (ECF No. 68-1).

(4) Anti-Adrenergic Receptor Antibodies

Dr. Steinman acknowledged that Dr. MacGinnitie was correct that molecular mimicry may be widespread in healthy normal individuals, but Steinman remained convinced that "molecular mimicry is a key mechanism in understanding how tolerance to 'self' structures like myelin proteins is broken." *Id.* at 1-4, 18. Dr. Steinman reemphasized what he said in his first report: "[o]ther genetic and environmental factors are necessary before these self-reactive immune responses to neural antigens like adrenergic receptors might lead to an autoimmune disease of the autonomic nervous system." *Id.* at 3-4. Dr. Steinman also observed that he has published nine publications on molecular mimicry from 1994-2016, whereas Respondent's experts have not published on the topic at all. *Id.* at 4-8.

b) Dr. Bingham

Dr. Steinman restated his belief that Petitioner does have autoimmune dysautonomia with inappropriate tachycardia. *Id.* at 19. Dr. Steinman reiterated his reliance on the *Althen* criteria. *Id.* Finally, Dr. Steinman defended the timing and latency before induction of the autoimmune response elicited in mice, and stated that he "relied on the criteria in humans from the IOM report on Adverse Vaccinations" that Dr. Bingham himself considered more stringent than *Althen*. *Id.* at 20.

5. Dr. MacGinnitie's Second Report

Respondent responded to Dr. Steinman's second report by submitting another report by Dr. MacGinnitie. *See* Resp't's Ex. E (ECF No. 70-1). Dr. MacGinnitie referred to "a very recent article" that concludes "at this time there is no conclusive evidence support [sic] a causal relationship between the human papillomavirus vaccine and POTS. Though a causal relationship has been postulated, it is of utmost importance to recognize that while temporal associations may be observed, conclusion of causality cannot be drawn from case reports and case studies due to the small sample size and lack of a control population." *Id.* at 4 (citing B. Butts, *Human Papillomavirus Vaccine and Postural Orthostatic Tachycardia Syndrome: A Review of Current Literature*, J. Child Neurology 1 (2017), filed as Ex. E, Tab 3 (ECF No. 70-4)). He also responded to Dr. Steinman's second report.

a) POTS and Autoimmunity

Dr. MacGinnitie reiterated that the studies cited by Dr. Steinman suggesting a possible autoimmune cause of POTS were unreliable. Resp't's Ex. E at 2-3 (ECF No. 70-1). Dr. MacGinnitie responded to Dr. Steinman's criticism that his opinions are contradictory by asserting that the premise that "POTS is not an autoimmune disease" was not inconsistent with the premise that "vaccines in Petitioner's theory are not associated with autoimmunity." *Id.* at 2. Dr. MacGinnitie also observed that he "could not find any report of POTS being successfully

treated with immunosuppressive drugs such as steroids, which are the typical therapy for autoimmune diseases." *Id.* at 3.

b) CellTrend Assay

Dr. MacGinnitie defended his comments about the FDA, explaining that lab testing developed and performed by a single laboratory is regulated by the Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control (CDA), which can grant certification under the Clinical Laboratory Improvement Amendments (CLIA), but that a kit or test developed for use at multiple laboratories comes under FDA jurisdiction. *Id.* at 3-4. Dr. MacGinnitie emphasized that the CellTrend assay has neither CLIA nor FDA certification. *Id.* at 4. Dr. MacGinnitie also noted that the Loebel and Li articles present "no data relating the mild elevation of auto-adrenergic receptor antibodies in this case with POTS." *Id.* at 3.

Dr. MacGinnitie admitted that Dr. Steinman is correct that the panel of autoimmune antibodies sent by the dysautonomia specialists did not include anti-adrenergic antibodies, but pointed out that sending this panel instead of the CellTrend assay indicated the specialists did not find the CellTrend assay meaningful. *Id.* at 3. Dr. MacGinnitie observed that while Petitioner's CellTrend assay showed "significant levels of anti M4 antibodies," the article Dr. Steinman cited to demonstrates the antibodies' relevance "does not discuss antibodies against the M4 receptor or present evidence that these antibodies are involved in POTS." *Id.* Dr. MacGinnitie found the presence of two anti beta-cell antibodies in Petitioner irrelevant because they are not associated with POTS and are often seen in siblings of patients with Insulin-dependent Diabetes Mellitus, which Petitioner's sister has. *Id.*

c) Mouse Model

Dr. MacGinnitie reemphasized that the reliability of the mouse model Dr. Steinman relied on to support his theory of molecular mimicry is "at best questionable" because it "refers to injecting non-physiologic amounts of protein plus powerful adjuvants not used in humans (complete Freund's adjuvant) as a model (experimental autoimmune encephalomyelitis or EAE) for a disease (multiple sclerosis) that no one asserts JS suffers from." *Id.* at 2. Similarly, Dr. MacGinnitie found Dr. Steinman's newly cited Ufret-Vincenty report, that EAE can be induced by transferring T-cells between groups of mice, irrelevant, because "even if we accept his assertions regarding cross-reactivity and molecular mimicry," the report does not provide an animal model of autoimmune POTS and therefore cannot establish a foundation for his theory of molecular mimicry. *Id.*

d) Anti-Adrenergic Receptor Antibodies

Dr. MacGinnitie admitted that Dr. Steinman has published more on molecular mimicry, but emphasized that Dr. Steinman "does not present any data contradicting the fact that there is extensive overlap between viral and bacterial proteins and human ones which far exceed the degree of homology between proteins in Gardasil and adrenergic receptors that he cites in his original report." *Id.* at 1-2. Dr. MacGinnitie emphasized that "the presence of anti-adrenergic and anti-cholinergic antibodies is the sole evidence of autoimmunity potentially associated with

POTS in this case" and noted that this is a "crucial weakness" in Dr. Steinman's opinion because "immunity against self-antigens is common in the absence of clinical disease." *Id.* at 1.

6. Dr. Brawer

Petitioner responded to Dr. MacGinnitie's second report by filing three reports by Dr. Arthur E. Brawer. *See* Pet'r's Ex. 49 (ECF No. 92-1); Pet'r's Ex. 60 (ECF No. 93-1); Pet'r's Ex. 63 (ECF No. 100-1). Dr. Brawer concurred with the presence of adrenergic antibodies as one of the grounds for satisfying the *Althen* test. *See* Pet'r's Ex. 49 at 3 (ECF No. 92-1). However, Petitioner "chose[] not to rely upon his expertise in presenting her case" because "Dr. Brawer did not develop the adrenergic antibody approach any further." Pet'r's Mot., filed Dec. 6, 2021 at 3 (ECF No. 105).[18] Because Petitioner did not rely on Dr. Brawer, the Court will not summarize Dr. Brawer's reports.

Respondent filed two reports in response to Dr. Brawer. *See* Resp't's Ex. F (ECF No. 99-1) (Report by Dr. Andrew MacGinnitie, Ph.D.); Resp't's Ex. G (ECF No. 99-14) (Report by Dr. Peter M. Bingham). These reports dealt with arguments made by Dr. Brawer. Because Petitioner no longer relies on Dr. Brawer, there is no need to summarize these expert reports.

C. Chief Special Master's Decision

On December 6, 2021, Petitioner filed a Motion for Ruling on the Record, which included a request for a hearing. ECF No. 105. The Chief Special Master issued his Decision on July 15, 2022, denying entitlement to compensation under the Vaccine Act and denying Petitioner's request for a hearing. ECF No. 109 at 26, 37 ("It is simply not the case that every Vaccine Act Claim need be resolved by hearing—even where the [P]etitioner explicitly so requests."). Ultimately, the Chief Special Master found that Petitioner failed to show, "on the basis of th[e] medical record, that she experienced *any* arguably vaccine-caused disease or condition—and it is more likely her symptoms reflect somatization." *Id.* at 2 (emphasis in original). Further, the Chief Special Master emphasized that to "date, [*he has*] *never ruled that the HPV vaccine likely causes any form of dysautonomia*. The medical science that has been offered on this contention in case after case simply does not support that conclusion—and [he is] aware of no counter, persuasive analyses that would suggest the alternative." *Id.* at 36 (emphasis in original). He also provided "that *this particular case lacks reasonable basis going forward*" and warned that attorney's fees would not be awarded if Petitioner "opts to extend this claim's life further . . . ." *Id.* at 36 n.41 (emphasis in original).

[18] Petitioner's reluctance to rely on Dr. Brawer may have stemmed from Dr. Brawer's personal attacks on Respondent's experts. *See, e.g.*, Pet'r's Ex. 63 at 3 (ECF No. 100-1) ("[T]he tone of Dr. Bingham's report suggests that he himself may in part be suffering from a functional neurological disorder."). Respondent moved to strike Dr. Brawer's second report due to this language. *See* ECF No. 102. The Special Master denied the motion, but informed the Petitioner that this sort of language was "a reason for deeming the attacking expert's report to deserve less weight than an even-handed report would receive." ECF No. 104 at 2.

Petitioner timely filed a motion for review on August 14, 2022. ECF Nos. 112 & 114. Petitioner's numbered objections to the Decision are as follows:

Numbered Objection 1

The Special Master's Decision is arbitrary, capricious, an abuse of discretion and contrary to law in finding tachycardia cannot be deemed a primary condition compensable by the Vaccine Program (a "cognizable vaccine injury" (Dec. at 28-29, 30-32); *see Tarsell United States*, 133 Fed. Cl. 782, 794 (2017). While tachycardia might often be accompanied by other symptoms, the Decision identified no basis for denying its status as a primary condition or cognizable vaccine injury.

Numbered Objection 2

By prospectively denying the availability of attorneys' fees for the present Motion for Review, the Decision was arbitrary, capricious, an abuse of discretion and contrary to law. (Dec. at 36, fn. 41). Where the Decision determined for the first time that the Petition had lost reasonable basis, thus denying review or improperly burdening Petitioner with the costs of review, the special master interjected a chilling effect thereby undermining the Vaccine Act procedure for review and appeal established in 42 U.S.C. § 300aa-12(e), and violated judicial procedure prohibiting a judge from determining an appeal of his or her own decision. Title 28, Section 47.

Numbered Objection 3

The special master engaged in an arbitrary pattern of result-oriented and generalized factfinding that is unsupported by the medical record. The special master's arbitrary factfinding featured unfounded rejection or silent avoidance of objective medical evidence to allow the unsupported conclusion that petitioner's condition was a mental disorder. The Decision was arbitrary and capricious in summarily finding petitioner's condition was more likely a mental disorder than a physiological disorder in the face of a medical record that contained no straightforward evidence of a mental disorder diagnosis. The arbitrary pattern of factfinding was manifest in the Decision's one-sided interpretation of petitioner's objective testing, including the interpretation of medical findings of tachycardia, which were central to petitioner's case, but were cast by the special master as psychiatric (or "mental disorder") phenomena. (Dec. at 35).

Numbered Objection 4

The Decision is arbitrary, capricious and an abuse of discretion in its internally contradictory finding that dysautonomia might be attributable to an autoimmune process in rare cases such as the those in the present case, where anti-adrenergic antibodies caused heart rate increases, while simultaneously admonishing petitioners to avoid bringing claims involving HPV vaccination and allegations of dysautonomia. Thus, while acknowledging that in rare cases there may be a basis to pursue an autoimmune claim in connection with the vaccine's inducement of dysautonomia, the special master foreclosed this avenue of evidence entirely. Thus, the Decision was arbitrary in foreclosing the possibility that petitioner could prove the very same claim the court found potentially plausible. (Dec. at 36).

Numbered Objection 5

The special master's decision was arbitrary, capricious, and contrary to law in deeming petitioner's proffered medical theory of causation as insufficient. The Petitioner demonstrated a sufficient relationship between molecular mimicry and the increase in anti-adrenergic antibodies to satisfy Althen prong 1, contrary to the special master's holding (Dec. at 32).

Numbered Objection 6

The special master was arbitrary, capricious, and abused his discretion in denying an evidentiary hearing where the issue of petitioner's mental state and her behavior was central to the Decision's findings of fact. The abuse of discretion is evident where the special master found that preponderant evidence strongly supports the conclusion that "some other kind of mental disorder explains [petitioner's] symptoms" based on a medical record which reveals no clear psychiatric or psychological diagnosis of Petitioner. Thus, the special master abused his discretion in substituting a diagnosis that is absent from the medical record, while at the same time denying a hearing where the Petitioner could fully develop the issue of her mental state. (Dec. at 35-36).

ECF No. 112 at 1-3. Respondent filed its response on September 14, 2022. ECF No. 118. After reviewing the filings, the Court upholds the Chief Special Master's findings of fact and conclusions of law and sustains the Chief Special Master's decision.

II. DISCUSSION

A. Jurisdiction & Standard of Review

The United States Court of Federal Claims exercises jurisdiction to review vaccine decisions pursuant to § 300aa-12(e)(1) of the Vaccine Act. In reviewing a special master's decision, this Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). "Under the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." *Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353, 1355-56 (Fed. Cir.), *cert. denied*, 552 U.S. 816 (2007).

Specifically, "[f]indings of fact of the special master are reviewed under the arbitrary and capricious standard, conclusions of law are reviewed under the 'not in accordance with law'

standard, and discretionary rulings are reviewed under the abuse of discretion standard." *Broekelschen v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 336, 343 (2009), *aff'd*, 618 F.3d 1339 (Fed. Cir. 2010) (citations omitted). "An abuse of discretion may be found when (1) the court's decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision is based on an erroneous conclusion of the law; (3) the court's findings are clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision." *Simmons v. HHS*, 875 F.3d 632, 635 (Fed. Cir. 2017) (quoting *Hendler v. U.S.*, 985 F.2d 1364, 1380 (Fed. Cir. 1991)). As such, the Vaccine Act "provide[s] for a limited standard for appeal from the [special] master's decision" and its legislative history shows "that this procedure [should not] be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

Indeed, the arbitrary and capricious standard is "well understood to be the most deferential possible." *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). As such, when evaluating factual findings of the special master, this Court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *see also Hodges v. Sec'y of Dept. of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) ("[O]n review, the Court of Federal Claims is not to second guess the Special Master[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process."). "Rather, as long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, [the Court is] compelled to uphold that finding as not being arbitrary or capricious.'" *Porter*, 663 F.3d at 1249 (first alteration in original and second alteration added) (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)). Where "the special master has 'considered the relevant evidence of record, drawn plausible inferences, [and stated] a rational basis for the decision,' reversible error is extremely difficult to establish." *Silva v. Sec'y of Health & Human Servs.*, 108 Fed. Cl. 401, 405 (2012) (quoting *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

B. Vaccine Act Legal Standard

To receive compensation under the Vaccine Act, petitioner must prove either 1) that she suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – that corresponds to the vaccination received, or 2) that she suffered an injury that was caused-in-fact by a vaccine. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) & 300aa-11(c)(1). Here, Petitioner does not allege, and the record does not show, that she suffered a "Table Injury" caused by the Hep. A or HPV vaccination. *See* Vaccine Injury Table, 42 U.S.C. § 300aa-14. Rather, Petitioner argues that these vaccinations caused her injury in-fact.

In *Althen v. Secretary of Health & Human Services*, the Federal Circuit articulated a three-part test outlining a petitioner's burden to establish causation-in-fact under the Vaccine Act. 418 F.3d 1274, 1278 (Fed. Cir. 2005). To prove causation-in-fact, a petitioner must:

> [S]how by preponderant evidence that the vaccination brought about her injury by providing (1) a medical theory causally

> connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id.; *see also Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1355 (Fed. Cir. 2019) (holding that a petitioner must "prove[] all three *Althen* prongs by a preponderance of the evidence"); 42 U.S.C. § 300aa–13(a)(1)(A) (Petitioner must prove causation-in-fact "by a preponderance of the evidence."). "A careful reading of *Althen*, shows that each prong . . . is decided relative to the injury: (1) medical theory connecting the vaccination to the injury; (2) cause and effect showing the vaccination was the reason for the injury; and (3) proximate temporal relationship between the vaccination and the injury." *Broekelschen v. Sec'y of HHS*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (citing *Althen*, 418 F.3d at 1278). Identifying the injury is therefore a prerequisite to the analysis. *Id.*

The Federal Circuit has "held that causation-in-fact in the Vaccine Act context is the same as the 'legal cause' in the general torts context." *De Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1351 (Fed. Cir. 2008). "Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is 'a substantial factor in bringing about the harm.'" *Id.* (quoting the Restatement (Second) of Torts § 431(a)). Accordingly, to establish causation, "[Pe]titioner must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Id.* at 1351 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). A "'substantial factor' standard requires a greater showing than 'but for' causation." *Id.* (quoting *Shyface*, 165 F.3d at 1352). But a petitioner is not required to establish the causation to a scientific certainty:

> Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is "logical" and legally probable, not medically or scientifically certain.

Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). The Vaccine Act permits proof of causation through "the use of circumstantial evidence envisioned by the preponderance standard." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (internal citation and quotation marks omitted). Petitioner's claim must be "substantiated by medical records or medical opinion." *Althen*, 418 F.3d at 1279.

III. DISCUSSION

Petitioner presents six numbered objections for this Court's review. Objections 1 and 3 challenge the Chief Special Master's finding that Petitioner failed to establish a cognizable injury compensable under the Vaccine Act. Objection 5 challenges the Chief Special Master's finding that, although he need not engage in a thorough *Althen* analysis, Petitioner failed to meet her burden under *Althen* prong 1. Objection 4 challenges the Chief Special Master's rejection of the scientific evidence supporting the viability of Petitioner's theory of causation. Objection 6

challenges the Chief Special Master's decision to decide the case on the record without a hearing. Finally, Objection 2 challenges the Chief Special Master's prospective denial of attorney's fees. *See* ECF No. 112 at 1-3.

A. The Chief Special Master's finding that Petitioner failed to establish a cognizable vaccine injury is neither arbitrary nor capricious.

Petitioner argues the "Special Master's Decision is arbitrary, capricious, an abuse of discretion and contrary to law in finding tachycardia cannot be deemed a primary condition compensable by the Vaccine Program." ECF No. 112 at 1 (citing ECF No. 109 at 28-29, 30-32). Specifically, Petitioner claims "[w]hile tachycardia might often be accompanied by other symptoms, the Decision identified no basis for denying its status as a primary condition or cognizable vaccine injury . . . ." *Id.* Further, Petitioner alleges "an arbitrary pattern of result-oriented and generalized factfinding that is unsupported by the medical record . . . [which] featured unfounded rejection or silent avoidance of objective medical evidence to allow the unsupported conclusion that petitioner's condition was a mental disorder." *Id.* at 2. According to Petitioner, the "medical record . . . contained no straightforward evidence of a mental disorder diagnosis. . . . [T]he Decision's one-sided interpretation of petitioner's objective testing, including the interpretation of medical findings of tachycardia . . . w[as] cast by the special master as psychiatric (or "mental disorder") phenomena[,]" resulting in arbitrary factfinding. *Id.* at 2 (citing ECF No. 109 at 35).

It is well established that the Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). Petitioner must, therefore, "show by a preponderance of the evidence that she suffered from [a] medically recognized 'injury,' not merely a symptom or manifestation of an unknown injury." *Lombardi*, 656 F.3d at 1353. "If the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." *Id.* at 1352 (citing *Broekelschen*, 618 F.3d at 1346). This duty "is mandated by the Vaccine Act, which creates a cause of action for persons suffering a 'vaccine-related injury . . . .'" *Id.* (citing 42 U.S.C. § 300aa-11(a)).

The Chief Special Master found that although the "medical record . . . strongly establishes that Petitioner regularly sought medical treatment, often on an emergency basis, after her vaccinations in 2015[,] . . . that record simply does not preponderantly establish any actual *injury* that could be grounds for a Program claim." ECF No. 109 at 28 (emphasis in original). Respondent argues the Decision is "supported by the absence of reliable evidence pointing to a physiological condition, such as a dysfunctional autonomic nervous system, that otherwise persuasively explains her condition." ECF No. 118 at 15-16. Specifically, the Chief Special Master found Petitioner "was never legitimately diagnosed with POTS" and her "other reported symptoms—whether characterized as 'inappropriate tachycardia or something else [(e.g., dysautonomia)]—do not, individually or collectively, amount to a cognizable condition of any kind that could be shown to be vaccine-caused." ECF No. 109 at 29. Although Petitioner exhibited symptoms *suggestive* of injury, such as increased heart rate and blood pressure levels, no "testing evidence has been filed that would confirm the diagnosis." *Id.* "At most," the Chief Special Master explains, "Respondent's expert Dr. Bingham allowed the *possibility* that the

November [2015 tilt-table] testing could support POTS—but that is not the same as an admission (consistent with the preponderant standard applicable herein) that it was likely." *Id.*

Petitioner argues that "a close review of the record reveals a clear pattern of illness—tachycardia and arrhythmia related to autonomic dysfunction." ECF No. 114 at 23. But Petitioner's symptoms, as Dr. Bingham observed, "were consistently non-specific" and "transient/intermittent[19]—and this is especially true of the purported 'inappropriate tachycardia.'" ECF No. 109 at 29. Petitioner explains that tachycardia typically applies "to a heart rate above 100 beats per minute" and sinus tachycardia, which originates in the sinus node, "is normal during exercise or anxiety and occurs abnormally associated with shock, hypotension, hypoxia, congestive heart failure, fever, and various high output states." ECF No. 114 at 1 n.1. Such sinus tachycardia "can in some instances be inappropriate or pathologic." *Id.* Therefore, Respondent emphasizes the Chief Special Master's finding that sinus tachycardia, in some cases, may merely reflect a normal physiological response to stressors—such as anxiety or exercise—and is not in each case necessarily injurious or inappropriate. *See* ECF No. 109 at 29. And "while Petitioner might have *displayed* occasions of post-vaccination tachycardia at times in th[e] record, it cannot be deemed to be a persistent condition that could reasonably be linked to vaccination." *Id.*; *see, e.g.*, Pet'r's Ex. 18 at 1-3 (ECF No. 18-1) (autonomic testing performed in connection with tilt-table test did not identify measurable orthostatic intolerance). That Petitioner's physicians prescribed medication for her condition does not, by itself, "verify[] the validity of the diagnoses of inappropriate sinus tachycardia and autonomic disorder." ECF No. 114 at 26. Nor does the fact that Petitioner's heart rate rose by more than 40 points during the November 2015 tilt-table test establish a persuasive diagnosis for POTS. *See* Pet'r's Ex. 18 at 1-3 (ECF No. 18-1). In the end, the Chief Special Master weighed the record evidence of tachycardia and this Court does not find any basis to disturb that weighing of the evidence.

Similarly, while Petitioner reported "clonic-tonic seizures" following receipt of the Hep. A and Gardasil vaccinations, her medical records reflect diagnoses of "pseudoseizures" and related manifestations of an underlying psychological condition. Pet'r's Ex. 6 at 4, 38, 40-42, 80, 130-131, 134 (ECF No. 6-7); Pet'r's Ex. 12 at 11 (ECF No. 7-4). Petitioner argues "there was never a confirmed psychiatric diagnosis, other than 'anxiety,' which . . . is frequently seen in POTS and dysautonomia[] disorders [and where] patients 'may be incorrectly labeled as having panic disorder or chronic anxiety.'" ECF No. 114 at 29 (citing Pet'r's Ex. 25, Phillip Low et al., Postural Tachycardia Syndrome (POTS), *J Cardiovasc Electrophysiol. 2009 March; 20(3): 352–358.* ("Patients with orthostatic intolerance often present with complaints of exercise intolerance, lightheadedness, diminished concentration, tremulousness, nausea and recurrent syncope, *and may be incorrectly labeled as having panic disorder or chronic anxiety*.")). However, the Chief Special Master described in detail repeated instances where physicians evaluated Petitioner, expressed the opinion that her symptoms were likely psychological in nature and related to anxiety, and failed to identify an underlying physiological condition. *See* ECF No. 109 at 3-6.

[19] Petitioner's argument that "[t]he Decision elevated [her] burden of proof by requiring an unrealistic and unreachable level of proof showing *continuous* tachycardia" is similarly without merit. ECF No. 114 at 23. The Chief Special Master considered the transient and intermittent nature of Petitioner's symptoms in light of her medical record as a whole, rather than as a dispositive factor in rendering his Decision.

To be sure, "[n]o formal medical testing ever later confirmed the presence of any epileptic etiology or factors that might cause seizure activity—and in fact the absence of such evidence was clear not long after the relevant vaccinations." *Id.* at 29; *see* Pet'r's Ex. 6 at 130 (ECF No. 6-7); Pet'r's Ex. 9 at 64-68 (ECF No. 7-1). Again, the Court will not reweigh the record evidence.

Petitioner contends that "[t]here is nothing in the Decision that controverts the medical record evidence showing a dysautonomia based tachycardia. A finding of arrhythmia caused by Gardasil . . . has been validated as a 'cognizable' or primary vaccine injury in Court of Claims and Office of Special Masters decisions." ECF No. 114 at 29 (citing *Tarsell v. United States*, 133 Fed. Cl. 782 (2017)). However, the Special Master must "evaluate[] the utility of evidence differently in light of all facts relevant in a specific claim," and "a different evidentiary record can lead to different outcomes." *Rickett v. HHS*, 468 F. App'x 952, 959 (Fed. Cir. 2011). And it is reasonable to conclude that "[b]ecause the facts of *Tarsell* differ widely from the facts of the present case, a different outcome is warranted." ECF No. 118 at 15.

In *Tarsell*, Petitioner developed acute disseminated encephalomyelitis within days of receiving the tetanus-diphtheria-acellular-pertussis vaccination and suffered unexpected death only weeks later. *Tarsell*, No. 10-251V, 2017 WL 4583233, at *16 (Fed. Cl. Sept. 25, 2017). Not only did the Court find that Petitioner successfully established her claimed injury, but it also found "preponderant evidence of a logical sequence of cause and effect," connecting Petitioner's injury to her receipt of the vaccination. *Id*. at *16. Whether the Petitioner's arrythmia was a cognizable injury, based on the facts in that case, was not at issue. Conversely, here, upon weighing the evidence in the record, the Chief Special Master found "numerous, credible instances in which treaters proposed or surmised that Petitioner's symptoms had a psychologic component, reflecting either somatization, excessive anxiety, or some other mental trauma that precipitated a heightened heart rate and other panic-like symptoms." ECF No. 109 at 30 (citing Pet'r's Ex. 6 at 80 (August 21, 2018 visit with treaters finding Petitioner experienced pseudoseizure); Pet'r's Ex. 7 at 36 (ECF No. 6-8) (August 23, 2015 neurology consult diagnosing Petitioner with acute anxiety disorder); Pet'r's Ex. 9 at 47 (ECF No. 7-1) (September 22, 2015 neurology evaluation discussing recent stressors in Petitioner's life that may have caused seizure-like activity); Pet'r's Ex. 13 at 213 (ECF No. 9-1) (September 19, 2015 neurology consultation with a clinical impression of "probable pseudo-seizures", "stress related psycho-somatization or somatization", and "probable anxiety associated panic")). Accordingly, the Chief Special Master had reasonable basis to find "[t]he possibility of a psychological factor as causal of Petitioner's symptoms[,] [which] also strongly negates the conclusion that Petitioner did in fact experience something that reasonably could be seen [as] a potential vaccine injury." ECF No. 109 at 31.

Petitioner complains that "[i]n glossing over the persistent findings of objective evidence over an extended time period showing tachycardia, arrhythmia, dysautonomia and autoimmunity, in favor of a vague special master diagnosed 'mental disorder', the Court has engaged in an arbitrary exercise of selective citation to the record and abused its discretion . . . ." ECF No. 114 at 30-31. To illustrate, Petitioner discusses the Chief Special Master's discreditation of her February 2016 CellTrend laboratory results, which showed elevated levels of adrenergic and muscarinic antibodies. Pet'r's Ex. 16 at 1-2 (ECF No. 12-2). Petitioner argues, because "it cannot be determined on th[e] records that she possesse[d] these specific antibodies in the

immediate one to ten days after the receipt of the HPV vaccine[,]" the Decision "imposed, without explanation or justification, a heightened burden of proof on Petitioner to show the presence of antibodies within one to ten days of vaccination." ECF No. 114 at 36 (citing ECF No. 109 at 31). Further, Petitioner believes the Chief Special Master ignored the "dramatic increase [of antibodies] over time" as evidenced by testing showing increased antibody levels in March 2020, *see* Pet'r's Ex. 37 at 1 (ECF No. 77-2), which "signifies that Petitioner experienced an autoimmune reaction rather than a manifestation of psychiatric symptoms," ECF No. 114 at 36. However, the Chief Special Master carefully considered and weighed this evidence and did not find it supportive of Petitioner's claim. To be sure, "neither [P]etitioner's treating providers, nor her own expert, Dr. Steinman, ever related these results to [P]etitioner's post-vaccination symptoms." ECF No. 118 at 17. And, showing elevated antibodies nearly five years later does not sufficiently establish a causal connection between Petitioner's claimed injuries, which began within days of her vaccination.

The Chief Special Master clearly considered Petitioner's antibody testing between 2016 and 2020 but did not find it persuasive. According to the Decision: "I give little weight to the testing results Petitioner obtained in 2020—almost five years after her vaccination, and nearly four years after the case was filed—suggesting she possessed certain anti-adrenergic autoantibodies theorized to cause dysautonomia." ECF No. 109 at 31. The Chief Special Master found other record evidence more compelling. For example, he assessed Petitioner's November 2015 neurological exam, where her autoimmune antibody panel was negative, and her symptoms were described as consistent with a panic disorder. *Id.* at 7-8; Pet'r's Ex. 18 at 1-3 (ECF No. 18-1). The Chief Special Master also acknowledged reasonable objections raised by Dr. MacGinnitie, who questioned the legitimacy of leveraging anti-adrenergic autoantibody test results to support a causal theory for dysautonomia. ECF No. 109 at 31 n.35. It is not for this Court to reweigh that evidence and it will not do so. The Decision also recognized that although Petitioner's "infectious evaluation seemed to allow for a possible autoimmune injury, [it] more expressly discounted dysautonomia, noting that Petitioner displayed only 'minor orthostatic changes which are not consistent with POTS or significant autonomic instability.'" *Id.* at 30 (quoting Pet'r's Ex. 4 at 3 (ECF No. 6-5)). This did not impose a heightened standard on Petitioner; rather, the Chief Special Master had sound footing to determine that the totality of Petitioner's medical record, including the temporal distance between her receipt of the vaccination and the laboratory testing, weighed against her claim. It was therefore neither arbitrary nor capricious for the Chief Special Master to find "no record evidence . . . that Petitioner possessed these antibodies in the fall of 2015 . . . [and to] not add any legitimate weight to the contention that Petitioner did in fact experience an actual injury post-vaccination." *Id.* at 31.

Finally, Petitioner argues that, after multiple visits to the emergency room where she exhibited symptoms of tachycardia, Dr. Lefkowitz "identified a persistent pattern of tachycardia and other autonomic symptoms, which was verified by objective testing on the date of examination." ECF No. 114 at 24; Pet'r's Ex. 12 at 1, 10-11 (ECF No. 7-4) (diagnosing Petitioner with "Shy-Drager syndrome," symptoms consistent with "inappropriate sinus tachycardia," and "autonomic disfunction due to the HPV vaccine"). Specifically, Petitioner references the Zio Patch Electrocardiography Monitoring Report reviewed by Dr. Lefkowitz, which showed instances of premature atrial and ventricular contractions and paroxysmal atrial tachycardia. *See* Pet'r's Ex. 12 at 4 (ECF No. 7-4). However, the Chief Special Master observed

that "Dr. Lefkowitz not only appears to have relied heavily on Petitioner's self-reported history (which did not emphasize the extent to which her prior multiple ER visits never corroborated an underlying psychologic explanation for her episodes)" but he also did not have the benefit of the tilt-table results to include in his evaluation. ECF No. 109 at 30. More importantly, the Chief Special Master did not ignore the record evidence; rather, after reviewing Petitioner's comprehensive medical history—including the objective evidence—he recognized multiple instances of tachycardia. But he concluded that the record did not establish that Petitioner's episodes were pathologic in this case. Accordingly, he determined that, even if tachycardia can be inappropriate in *some cases*, Petitioner failed to preponderantly establish a cognizable injury here. He also found Dr. Lefkowitz's assessment incomplete, and grounded, at least in part, on Petitioner's self-report of her own medical history, which he believed merited less weight. The Chief Special Master acknowledged that "[w]hat one treater is told, or understands, about a claimant's history at a certain point in time can be incomplete, or reflect a tentative, initial diagnostic proposal that later on is not confirmed by . . . testing or the course of the injured party's medical disease."[20] *Id.* Therefore, in weighing the totality of the evidence, it was reasonable for the Chief Special Master to conclude that Dr. Lefkowitz's diagnosis appeared "speculative and . . . in any event unsubstantiated by the record." *Id.*

"Clearly it is not . . . the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Munn*, 970 F.2d at 870 n.10. Indeed, the Court will not "examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." *Id.* The Court must therefore review the Chief Special Master's decision to determine whether it is reasonably based on the evidence in the record. *Milik*, 822 F.3d at 1376. Here, the Chief Special Master sufficiently considered the record evidence and articulated a reasonable basis for finding Petitioner failed to demonstrate, by a preponderance, that she "experienced *any* cognizable illness or injury that could be attributed to vaccination in any manner other than temporally (an insufficient basis for entitlement, as well-recognized in the Program)." ECF No. 109 at 31. And it is insufficient to merely highlight contrary evidence on review when it is the charge of the Chief Special Master, rather than this Court, to weigh and assess its credibility. The Chief Special Master appropriately considered the record evidence and his conclusion was not arbitrary, capricious, or otherwise not in accordance with law.

B. The Chief Special Master's finding that Petitioner failed to meet her burden under *Althen* Prong 1 is neither arbitrary nor capricious.

Petitioner complains the Chief Special Master's Decision "was arbitrary, capricious, and contrary to law in deeming [her] proffered medical theory of causation as insufficient . . . [where she] demonstrated a sufficient relationship between molecular mimicry and the increase in anti-adrenergic antibodies to satisfy *Althen* prong 1 . . . ." ECF No. 112 at 2-3. If a Special Master determines that the record evidence does not support the injury alleged, the Special Master need

[20] The Chief Special Master also indicated Dr. Lefkowitz's diagnosis of Shy-Drager syndrome undercut his credibility, as this theory was rejected by both Parties' experts, and largely abandoned by Dr. Lefkowitz in later years. ECF No. 109 at 30; *see, e.g.*, Pet'r's Ex. 33 at 27 (ECF No. 60-1) (raising myxoma as a new diagnosis in October 2017).

not "undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by 'reputable medical or scientific explanation,' by which a vaccine can cause the kind of injury that the petitioner claims to have suffered." *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1365 (Fed. Cir. 2012) (quoting *Althen*, 418 F.3d at 1278). Indeed, absent sufficient "proof of the asserted injury, the theory of causation is *a priori* unreliable and unsupported by the evidence, and it is unnecessary to go through the remaining *Althen* factors." *Hughes v. Sec'y of HHS*, 154 Fed. Cl. 640, 650 (2021) (citing *Broekelschen*, 618 F.3d at 1346). It was reasonable for the Chief Special Master to conclude that Petitioner failed to establish a compensable injury, and therefore a thorough *Althen* analysis was not required. For completeness, however, the Chief Special Master provided an *Althen* prong 1 analysis.

"Under the first [*Althen*] prong, a petitioner must demonstrate that the vaccine at issue can cause the injury alleged." *Greene v. Sec'y of Health & Human Servs.*, 146 Fed. Cl. 655, 663 (2020) (citing *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006)). To make this showing, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" *Broekelschen*, 618 F.3d at 1345 (quoting *Knudsen*, 35 F.3d at 548–49). "The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). Petitioner argues that "Dr. Steinman has painstakingly shown how his theories of causation, especially his molecular mimicry theory, is based on a 'sound and reliable medical or scientific explanation.'" ECF No. 114 at 40 (quoting *Boatmon*, 941 F.3d at 1351. Specifically, Petitioner cites precedent embracing molecular mimicry "as a reliable scientific mechanism for explaining the pathophysiology of certain immune-mediated conditions, including many demyelinating disorders." ECF No. 114 at 41 (quoting *Morgan v. Sec'y of Health & Human Servs.*, No. 15-1137V, 2019 WL 7498665, at *19 (Fed. Cl. Dec. 4, 2019), *review denied, decision aff'd*, 148 Fed. Cl. 454 (2020).

Dr. Steinman grounded his argument on theoretical homology between the HPV vaccine and nerve receptors, theorizing that the "HPV and Hepatitis A vaccines could elicit T cell immunity to significant stretches of the alpha-adrenergic receptor . . . [which] can spread to other regions of the molecule." Pet'r's Ex. 28 at 15 (ECF No. 49-1). However, the Chief Special Master found "insufficient reliable corroborative proof supporting the conclusion that the homology is *meaningful* from a pathogenic sense. Merely showing via BLAST searches that some homology exists between amino acid sequences in the HPV vaccine components and nerve cells," he explains, "does not amount to a preponderant showing that the vaccine can produce antibodies that will likely cross-react against those cells." ECF No. 109 at 32. The Chief Special Master also considered, and accepted, Dr. MacGinnitie's opinion that, "although amino acid sequential/component homologies are easily demonstrated in nature, . . . their presence does not also mean concurrent cross-reactivity is inevitable." *Id.* To this end, he found that Respondent's experts "persuasively established that the vaccines at issue were highly *unlikely* to cause POTS specifically or orthostatic intolerance generally." *Id.* Rather, he concluded that "the medical records filed in this case reliably suggest that Petitioner's symptoms were more likely attributable to somatization or some anxiety condition, rather than an independent illness, vaccine-caused or not." ECF No. 109 at 34 (citing Pet'r's Ex. 7 at 224, 226–27, 233 (ECF No. 6-8) (August 20, 2015 ER visit complaining of anxiety, hyperventilation, and a panic attack);

Pet'r's Ex. 9 at 47 (ECF No. 7-1) (September 22, 2015 neurology evaluation noting the recent stressors in petitioner's life may have caused seizure-like activity); Pet'r's Ex. 13 at 213 (ECF No. 9-1) (September 19, 2015 neurology consultation stating the clinical impression is "probable pseudo-seizures", "stress related psycho-somatization or somatization", and "probable anxiety associated panic")). Finally, he explained "[t]he contention that the HPV vaccine could be associated with 'clonic-tonic' seizures or comparable movements is also thin . . . [as it is] largely (if not wholly) . . . derived from the HPV vaccine package insert[,][21] . . . [which is not] particularly probative evidence for injury causation . . . ." ECF No. 109 at 33.

It is well settled that the "Special Master has discretion to determine the relative weight of evidence presented, including contemporaneous medical records and oral testimony." *Whitfield v. Sec'y of HHS*, 154 Fed. Cl. 167, 190-91 (2021) (citing *Hibbard*, 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict)). Here, the Chief Special Master considered expert theories connecting the HPV vaccine and nerve receptors, but, on multiple occasions, found this theory "wanting because (a) it was not reliably shown that the vaccine could likely trigger the production of offending autoantibodies, or (b) the claimant's injury was not established to fall into the narrow category of autoimmune-driven POTS (which is almost exclusively *not* an autoimmune condition.)." ECF No. 109 at 32. The Chief Special Master weighed, and rejected, "opinion[s][22] to this end in many such cases" where experts opined "that the HPV vaccine can result in the production of autoantibodies sufficient to cause POTS through an autoimmune process—more often than not alleged to interfere with certain adrenergic nerve receptors." *Id.* at 31-32. He also determined, while the medical record demonstrates post-vaccination instances of transient tachycardia, the causation "theory offered by Petitioner was not reliably-established—and is otherwise unpersuasive." *Id.* at 31.

In sum, "[u]nder the Vaccine Act, Special Masters are accorded great deference in determining the . . . reliability of expert witnesses." *Cedillo*, 617 F.3d at 1347; *see Hanlon v. Sec'y of Health & Human Servs*., 191 F.3d 1344, 1349 (Fed. Cir. 1999). The Chief Special Master exhaustively detailed the medical records, expert opinions, and medical literature, and sufficiently articulated a rational basis for Petitioner's failure to meet her burden under *Althen* prong 1. ECF No. 109 at 32 ("[N]othing offered in this case by Petitioner or her experts provides more recent or more reliable evidence supporting the conclusion that the HPV vaccine might cause POTS (or any . . . autonomic-associated symptoms for that matter).").

[21] The Chief Special Master also explains that the HPV package insert is specific to syncope, which generally occurs "*close-in-time* to vaccination." ECF No. 109 at 33 (finding the 15-minute observation recommendation on the insert "cannot reasonably be read to suggest that the HPV vaccine is associated with a persistent risk of syncope"). According to the Decision, however, there is no persuasive evidence of a close-in-time syncopal event. *Id.*

[22] *See, e.g.*, Pet'r's Ex. 23 (ECF No. 42-5) (emphasizing "that a temporal relationship between vaccination and symptom onset does not confirm causality" and "antibody presence does not confirm vaccine causality of symptoms").

C. The Chief Special Master's findings with respect to the viability of Petitioner's HPV claims are neither arbitrary nor capricious.

Petitioner contends that the Decision is internally inconsistent in "finding that dysautonomia might be attributable to an autoimmune process in rare cases . . . while simultaneously admonishing petitioners to avoid bringing claims involving HPV vaccination and allegations of dysautonomia." ECF No. 112 at 2 (citing ECF No. 109 at 36). Specifically, Petitioner argues that the Chief Special Master "forecloses [such claims] entirely" by providing that there is "no reasonable basis for Petitioner to pursue Review of the Entitlement Decision." ECF No. 114 at 38. In support, Petitioner explains that, "[i]t is reasonable to infer from the Decision's holding . . . that [while] proof could be developed in support of a dysautonomia claim[,] . . . there simply has not been enough knowledge and research yet generated to support such claims." *Id.* And such a "forward-looking prohibition on new cases is inappropriate" where "[t]he generalized state of scientific knowledge credited in the Decision . . . changes month to month . . . ." *Id.*

Respondent is correct that "the Chief Special Master "did not 'foreclose' future claims, but rather, forewarned counsel that attorney's fees will not be awarded *ad infinitum* for meritless claims that continue to present the same causal theory that has been rejected time and time again." ECF No. 118 at 27. Indeed, the Decision emphasizes that Petitioner's proposed causal theory has been evaluated, and consistently rejected, in multiple prior instances. ECF No. 109 at 36 ("*I have never ruled that the HPV vaccine likely causes any form of dysautonomia.*") (emphasis in original); *see id.* at 27 (citing prior cases). Specifically, the Chief Special Master has found that such "claims reflect merely a (literal) temporal 'coincidence' between vaccination and onset—something well recognized not to support causation." *Id.* at 36 (citing *Grant*, 956 F.2d at 1148). Further, the Chief Special Master explained that current "science suggest[s] 'dysautonomia' is generally not autoimmune in character, and not otherwise capable of being vaccine induced." *Id.* at 2. As such, Petitioner "conflates that Chief Special Master's recognition that some evidence has emerged that in very rare cases POTS *may* be attributable to an autoimmune process," although it is most commonly not considered attributable, with a connection between the HPV vaccination and dysautonomia. ECF No. 118 at 27, 29. Therefore, while recognizing that "medical science may someday reach more reliable conclusions about this subject matter that would present an occasion for reconsideration of [his] conclusions, that day has yet to come." ECF No. 109 at 36. In other words, the Chief Special Master simply made clear that the *current* science does not support Petitioner's theory. If the science changes, there is nothing in the Decision that precludes a successful claim.

"Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims." *Hodges*, 9 F.3d at 961. The standard of review attributed to this Court, therefore, "is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute." *Deribeaux v. Sec'y of Health & Human Servs*., 717 F.3d 1362, 1366 (Fed. Cir. 2013) (citing *Hodges*, 9 F.3d at 961). Accordingly, the Chief Special Master explains that the science, in its *current* state, does not support the vaccine theory of causation offered by Petitioner. ECF No. 109 at 27 ("[N]ot nearly enough is known about how

such an uncommon form of autoimmune-mediated POTS would occur to draw conclusions in Program cases sufficient to meet the preponderance level of evidence."). The Chief Special Master has seen no such persuasive, well written decisions that reach a contrary outcome, or which successfully establish that compensable tachycardia was vaccine-caused. *Id.* at 28. "At most, tachycardia has been a secondary symptom of *other* cognizable injuries." *Id.* And, while not foreclosing future claims based on these theories with new science supporting them, it is not arbitrary, capricious, or otherwise not in accordance with law for the Chief Special Master to find such cases will lack reasonable basis until the science changes.

D. The Chief Special Master did not abuse his discretion is deciding not to hold a hearing.

Petitioner argues the Chief Special Master "was arbitrary, capricious, and abused his discretion in denying an evidentiary hearing" when he attributed Petitioner's symptoms to "'some other kind of mental disorder[,]'" particularly where the "medical record . . . reveals no clear psychiatric or psychological diagnosis . . . ." ECF No. 112 at 3 ("[T]he special master abused his discretion in substituting a diagnosis . . . absent from the medical record"). In support, Petitioner explains that "[a]n evidentiary hearing usually provides petitioner opportunity to put on live testimony which aids the Special Master most in cases where witness credibility is in issue or where there is a need . . . to obtain information not contained in, or not self-evident from, the existing filings." ECF No. 114 at 50 (quoting *D'Toile v. HHS*, 132 Fed. Cl. 421, 433-34 (Fed. Cl. 2017), *aff'd mem.*, 726 Fed. Appx. 809 (Fed. Cir. 2018)). Petitioner believes this case warranted a hearing to allow exploration of divergent expert opinions, and in-depth discussion of her medical condition, e.g., as related to whether she had a "mental disorder" and whether her tachycardia was "transient." *Id.* at 44. Respondent explains that, under the Vaccine Act, Special Masters "promulgate rules that 'include the opportunity for parties to submit arguments and evidence on the record *without requiring routine use of oral presentations, cross examinations, or hearings*.'" *Kreizenbeck v. Sec'y of HHS*, 945 F.3d 1362, 1365-66 (Fed. Cir. 2020) (citing 42 U.S.C. § 300aa-12(d)(2)(D)). Indeed, "[t]here is no requirement that oral testimony be taken to resolve differences in scientific or expert opinion. Opportunity for confrontation or cross examination is not required." *Id.* at 1366 (quoting *Hale v. HHS*, 22 Cl. Ct. 403, 409 (Fed. Cl. 1991)).

"Special [M]asters have wide discretion in determining whether to conduct an evidentiary hearing. *Id.* at 1365 (citing 42 U.S.C. § 300aa-12(d)(3)(B)(v) (providing that a special master "*may* conduct such hearings as *may* be reasonable and necessary" (emphasis added)). This discretion is limited in instances where the record is not comprehensive or fully developed, creating a need for Special Masters to observe expert witnesses personally to assess their credibility. *See Murphy v. HHS*, No. 90-882V, 1991 WL 71500, at *2 (Cl. Ct. Spec. Mstr. Apr. 19, 1991). Respondent argues that Petitioner failed to offer a "credible basis for concluding that the Chief Special Master exceeded his discretionary authority in resolving this case . . . on the record. Petitioner makes no claim that the record was not fully developed . . . but rather, identifies a number of abstract benefits that a live hearing might provide." ECF No. 118 at 31. I agree. Where Petitioners are given a "full and fair" opportunity to present their case, *see Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 400–01 (1997), Vaccine Rule 8(d) permits Special Masters to "decide a case on the basis of written submissions without conducting an evidentiary hearing."

Here, the Chief Special Master articulated a rational basis for exercising his discretion to decide this case on the record. Specifically, he "was able to evaluate the evidentiary strength of [Petitioner's] asserted injury through a close review of the medical record" and determined that the "record overwhelmingly undermines the contention that [the HPV or Hep. A] vaccination harmed Petitioner." ECF No. 109 at 35. Rather, the Chief Special Master found that Petitioner failed to establish a cognizable injury, and there existed an alternative explanation for her symptoms. *Id.* He found this conclusion to be "self-evident from a careful review of the record itself, and did not require a hearing for their complete explication." *Id.* Accordingly, this Court concludes that the Chief Special Master did not abuse his discretion by opting to resolve the case on the record.

E. Petitioner's prospective demand for attorney's fees is not ripe for review.

In his Decision, the Chief Special Master provided that "counsel acts at his own risk if he opts to extend this claim's life further, such as through unnecessary motion for review or additional appeals." *Id.* at 36 n.41. He continued to warn that he would "not award any fees incurred for such work (although [he was] prepared to award fees reasonably devoted to the claim's prosecution up to this point)." *Id.* Petitioner argues that "[b]y prospectively denying the availability of attorneys' fees . . . the special master interjected a chilling effect thereby undermining the Vaccine Act procedure for review and appeal established in 42 U.S.C. § 300aa-12(e), and violated judicial procedure . . . ."[23] ECF No. 112 at 1-2. Indeed, 28 U.S.C. § 47 provides that "[n]o judge shall hear or determine an appeal from the decision of a case or issue tried by him." And prospectively determining that fees will not be paid should Petitioner seek review of his Decision effectively undermines judicial procedure. But this Court (and perhaps the Federal Circuit) is acting the judge of Petitioner's appeal, not the Chief Special Master.

To the extent the objection is that the Chief Special Master may not approve fees for this Court's (or the Circuit's) review, that objection is not yet ripe. "The case or controversy requirement of Article III of the United States Constitution prohibits federal courts from issuing advisory opinions or deciding disputes that are not concrete and adverse." *Massachusetts Bay Transp. Authority v. U.S.*, 21 Cl. Ct. 252, 257 (1990). "Although established under Article I, the Claims Court traditionally has applied the case or controversy requirement unless jurisdiction conferred by Congress demands otherwise." *Id.*; *see also C.W. Government Travel, Inc. v. U.S.*, 46 Fed. Cl. 554, 557-58 (2000). Respondent clarifies that "[a] claim is not ripe where it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." ECF No. 118 at 21 (citing *Armoring Service, Inc. v. U.S.*, 123 Fed. Cl. 309, 328 (2015)).

Petitioner has not submitted a request for attorney's fees and, unless such request is submitted and denied, this question is not ripe for review. The Chief Special Master's comment

[23] Petitioner argues that the determination this case lacks reasonable basis going forward "deprives petitioner of counsel or, if counsel proceeds, burdens counsel with the prospect of providing services without compensation for his or her labor, thereby obstructing the effective prosecution of the Petition on review or appeal." ECF No. 114 at 32. However, as previously explained in Section C herein, I do not find the Chief Special Master's holding with respect to this claim's viability—absent a change in the scientific evidence—to be arbitrary, capricious, or otherwise not in accordance with law.

therefore does not impede Petitioner's right to meaningful review and does not contravene Due Process and Equal Protection of the law.[24]

IV. CONCLUSION

For the reasons stated above, the Court **DENIES** the Petitioner's Motion for Review and **SUSTAINS** the Chief Special Master's decision. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Edward H. Meyers
Edward H. Meyers
Judge

[24] That said, the Court does have some concern about the blanket denial of fees for review of the Chief Special Master's decision. Simply finding Petitioner's experts unpersuasive is not generally a sufficient basis to find Petitioner lacked a reasonable basis to proceed. *See Heath v. HHS*, No. 08-86V, 2011 WL 4433646, at *7 (Fed. Cl. Spec. Mstr. August 25, 2011). The Court, however, will not resolve this matter until there is a fee petition and decision by the Chief Special Master fully explaining the denial of any portion of the fees sought for this review. To be clear, there is nothing improper with the Chief Special Master informing counsel in future cases that fees will not be awarded for cases brought on this theory, the only potential concern is with cutting off the reasonable basis to seek review in this case.