

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-878V

(to be Published)

HANNAH COMBS,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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Special Master Corcoran

Dated: February 15, 2018

Entitlement Decision; Human
Papillomavirus (“HPV”) Vaccine;
Vasovagal Syncope; Autonomic
Nervous System

Andrew D. Downing, Van Cott & Talamante, Phoenix, AZ, for Petitioner.

Debra A. Begley, U.S. Dep’t of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT¹

On September 22, 2014, Jenny Howard filed a petition seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”)² on behalf of her minor daughter, Hannah Combs (who become the named Petitioner after she reached the age of majority). Ms. Combs alleges that she experienced vasovagal/reflex syncope as a result of receiving doses of the Human Papillomavirus (“HPV”) vaccine on November 9, 2011; February 3, 2012; and September 13, 2012.

¹ This Decision will be posted on the Court of Federal Claims’s website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

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

An entitlement hearing in this matter was held on August 1, 2017, in Washington, DC. For the reasons stated below, I find that Petitioner has not established entitlement to a vaccine injury damages award. Petitioner’s causation theory – that the HPV vaccine could damage the autonomic nervous system - was scientifically unreliable and unpersuasive, and Petitioner was also unable to demonstrate, based upon her medical history, that her syncope was vaccine-caused, and/or that it occurred due to autonomic nervous system damage caused by a vaccine.

I. Factual Background

First Two HPV Vaccine Doses and Purported Initial Manifestations of Syncope

Ms. Combs received her first HPV vaccine dose on November 9, 2011, when she was 13. Her past medical history is significant for polycystic ovarian disease, hirsutism, hypothyroidism, anxiety, and depression. Ex. 2 at 9. She also had a prior traumatic experience that resulted in diagnoses of post-traumatic stress disorder (“PTSD”), hypervigilance, nightmares, dissociation, suicidal thoughts, anxiety, and depression. *Id.* at 52; *see generally* Ex. 11. At the time of her HPV immunizations, Ms. Combs was taking oral contraceptives and medication for depression. Ex. 4 at 17. The medical records make no reference to any reaction to the first HPV dose, although (as discussed below) Mrs. Howard has testified that Ms. Combs did begin to experience some initial symptoms. *See generally* Tr. at 9-10.

On February 3, 2012, Ms. Combs received her second HPV vaccine dose. Ex. 10 at 1. As with the first, the record is devoid of any mention of an immediate reaction to this vaccination. Almost seven weeks later, however, on March 16, 2012, Petitioner sought medical treatment after she fell during a hike in her backyard. Ex. 6 at 75. As the records reveal from that visit, Ms. Combs reported that she “fell over an embankment,” and as a result was experiencing pain in her lower back, neck, right hip, right shoulder, and right upper leg. *Id.* at 74. She further reported that during the fall she “hit her head and was unable to see at first,” and she had been suffering head pain ever since. *Id.* at 75.

Significantly, the medical record from this incident did not state that Ms. Combs had fainted, or had experienced any pre-syncope symptoms that could have caused her fall (although the fall occurred in the time period in which, according to Mrs. Howard, Petitioner was generally experiencing dizziness (Tr. at 13)). In addition, the location of Petitioner’s fall (her backyard) was a hilly area with notable elevation changes, and hence a location that a person might foreseeably fall even if she did not feel dizzy. Tr. at 50. Ms. Combs was assessed with a chest wall and cervical strain, and a knee and leg sprain. Ex. 6 at 79.

Several months passed without a need for medical treatment. Then, on June 4, 2012, Ms. Combs presented to the emergency room (“ER”) at the Paul B. Hall Regional Medical

Center in Paintsville, Kentucky, because she was feeling faint. Ex. 6 at 54. She reported a four-day history of headaches similar to ones she experienced in the past. *Id.* at 51. Specifically, while at work that day, she claimed to have felt as though she were going to pass out, and also experienced numbness and tingling in her legs and feet, plus shortness of breath while travelling to the hospital. *Id.* at 54. Upon evaluation, Ms. Combs’s vital signs indicated a 40 beats per minute (“bpm”) increase, and her blood pressure levels indicated systolic drop, coupled with a diastolic increase from 52 to 80, then back to 62. *Id.* at 55. Ms. Combs was diagnosed with a vasovagal reaction and discharged. *Id.* at 58.

Ms. Combs then visited her primary care physician, Dr. Rhonda Meadows, on June 15, 2012, at which time she reported the pre-syncopal event from earlier in the month that had resulted in her ER visit. Ex. 4 at 15. Mrs. Howard accompanied Petitioner to the examination, and at that time expressed the concern that Ms. Combs’s condition could be cardiac in nature. *Id.* An EKG showed sinus bradycardia³, but Holter monitor⁴ results were normal. *Id.* at 16. Ms. Combs subsequently saw Dr. Meadows four more times over the next year, but never reported any additional syncopal or pre-syncopal episodes. *Id.* at 7-16.

Third Dose and Additional Symptoms

On September 13, 2012, Ms. Combs received her third HPV vaccination. Ex. 10 at 1. The medical records reveal no reaction to the vaccine akin to what has been alleged in this case until November 13, 2012 (two months after), when Ms. Combs went again to the ER after she fainted at work. Ex. 6 at 28. In the course of being transported to the ER, emergency treaters noted that Petitioner’s blood sugar was low, and therefore gave her a tube of oral glucose. *Id.* While in the ER, her symptoms improved, and she was diagnosed with hypoglycemia and transferred to Cabell Huntington Hospital (“CHH”) for further care. *Id.* at 23.

Ms. Combs was an inpatient at CHH for a single night. In the course of being treated, she reported during a neurology consultation that she had been “having episodes once a week since April/May [two to three months after the second dose] where she feels like she is going to pass out, but hasn’t until last night.” Ex. 9 at 13. She described the episodes as “feeling dizzy, weak in her legs and right arm,” along with shortness of breath and feeling like her heart was racing. *Id.* At CHH she saw endocrinologist Dr. James Bailes, who noted that although Petitioner reported

³ Bradycardia is defined as “slowness of the heartbeat.” *Dorland’s Illustrated Medical Dictionary* at 245 (32nd ed. 2012) [hereinafter *Dorland’s*]. Sinus Bradycardia is a “slow sinus rhythm” evidenced by a heart rate of less than 60 bpm. *Id.* It is common in young adults and athletes, but can also indicate a possible disorder. *Id.*

⁴ A Holter monitor (named for American biophysicist Norman Jefferis Holter) is a small, wearable heart monitor used to track heart rhythm. *Holter Monitor*, Mayo Clinic, <https://www.mayoclinic.org/tests-procedures/holter-monitor/about/pac-20385039> (last accessed on Feb. 2, 2018). Holter monitors are traditionally used if a standard monitor, such as an electrocardiogram, cannot capture a suspected irregular heartbeat. *Id.*

experiencing dizziness and other pre-syncope symptoms in the past, she had never actually passed out until November 13, 2012. *Id.* at 11. Dr. Bailes remarked that all of Petitioner's symptoms "could be explained by hypoglycemia," and he recommended that she alter her diet. *Id.* at 12.

Besides Dr. Bailes, Ms. Combs also saw a cardiologist, Dr. Jack Stines, and conveyed to him that a couple of times per week she was experiencing "symptoms of dizziness, lightheadedness, and visual changes," along with chest pain and heart palpitations, but that these symptoms usually resolved on their own. Ex. 9 at 15. Dr. Stines noted that Petitioner's EKG was normal, and he opined that there "may be some component of vasovagal symptoms present here as it is very common in teenagers and her story is typical," expressing his agreement with Dr. Bailes's hypoglycemia diagnosis (which was officially recorded at discharge). *Id.* at 18, 28. She had a normal EEG⁵ as well, although the physician who administered the EEG, Dr. Mary Payne, noted that Petitioner was tachycardic and pale during the EEG, indicating possible autonomic dysfunction. *Id.* at 12, 29. Petitioner was discharged with a glucose monitor and advised to check her blood sugar when she experienced future pre-syncope events. *Id.*

On December 17, 2012, Ms. Combs returned to Dr. Stines as an out-patient, reporting continued episodes of syncope, weakness, dizziness, and lightheadedness. Ex. 3 at 1. It was noted that Petitioner's blood sugars remained low, at a 50-60 blood glucose level, during the episodes, and that she was working with Dr. Bailes to modify her diet to help manage her hypoglycemia. *Id.* Dr. Stines found no evidence of any heart problems, proposing instead that Petitioner's syncope was "explained by her hypoglycemia." *Id.* at 2. Dr. Bailes also maintained the same diagnostic opinion. Ex. 5. at 1. Ms. Combs was encouraged to increase her fluid intake, as this would help address any vasovagal component to her episodes. *Id.*

Symptoms in 2013 and Beyond

The medical records are silent for almost the next six months as to Petitioner's condition. On June 12, 2013, however, Ms. Combs had another ER visit after fainting again while at work. Ex. 8 at 106. She reported three episodes of syncope lasting three seconds each, as well as symptoms consistent with what she had previously related in her prior ER visits (i.e., shortness of breath, chest pain, and heart palpitations). *Id.* Petitioner also had a brief episode of shaking while she was passed out, although her treating physicians did not deem it consistent with a seizure. *Id.* at 109. Ms. Combs was diagnosed with a vasovagal syncope and discharged. *Id.* Then, on June 13, 2013, during a visit with Dr. Tiffany Mills, Mrs. Howard expressed the concern that Petitioner may have been having seizures. Ex. 4 at 5. In particular, she reported witnessing an event in the ER the day before in which Ms. Combs had "turned pale and her eyes rolled back in her head and she began jerking her arms and legs." *Id.*

⁵ An EEG or electroencephalogram is an instrument used to perform an encephalography. *Dorland's* at 600. An encephalography is a recording that measures electric currents in the brain by way of electrodes attached to the scalp. *Id.*

Dr. Mills admitted Petitioner to the University of Kentucky Hospital (“UKH”) for further evaluation. Ex. 4 at 6. Upon admission, Ms. Combs reported having suffered between seven and ten episodes of fainting or near-fainting since November 2012 (two months from the date of her final HPV dose), although as previously noted there are no medical records of any such instances from most of the first half of 2013. Ex. 7 at 62. She described the June 12, 2013, episode as having occurred at work three hours after she ate breakfast, and that she felt “weak, started to have tunnel vision, SOA [shortness of air], heavy chest and was gasping, before she passed out.” *Id.* at 62. Mrs. Howard added that per the store manager’s report, Ms. Combs had lost consciousness three times over a five-to-ten minute period. *Id.*

While at UKH, Ms. Combs had a consultation with child psychiatrist, Dr. Kimberly Robinson, and reported that sometimes her episodes were triggered by stress and anxiety, but that other times the symptoms occurred without an identifiable trigger. Ex. 7 at 52. Dr. Robinson opined that “given [petitioner’s] past history of trauma and anxiety, it is likely . . . that her syncopal episodes may be due to panic attacks with hyperventilation.” *Id.* at 56. Dr. Robinson strongly recommended that petitioner restart therapy and increased her antidepressant medication. *Id.* During a neurology consultation at UKH, Ms. Combs stated that taking hot showers often triggered her episodes. *Id.* at 57.

Petitioner’s mother also commented to the neurologist that during one of petitioner’s shaking episodes, petitioner was shaking so violently, it almost knocked her out of bed. Ex. 7 at 57. The neurologist wrote “jerking intense enough to take patient off bed, is concerning for pseudoseizure vs. syncope.” *Id.* at 59. But following a normal EEG, the neurologist decided not to place petitioner on anti-seizure medication. *Id.* In summarizing Ms. Combs’s prior history, the neurologist noted that she had experienced “multiple episodes of classic syncope: feels hot, gets tunnel vision, loses consciousness, if she sits down she can stop the spell from progressing to full loss of consciousness.” *Id.* at 49. The discharge diagnoses included syncope and collapse, panic attack, anxiety, and PTSD. *Id.* at 62-63.

The next filed medical record is from April 5, 2014, when Ms. Combs went to the ER complaining of a panic attack. Ex. 6 at 7. She was feeling anxious, had trouble breathing, was shaking, and her chest hurt. *Id.* After receiving Ativan,⁶ however, her symptoms resolved. *Id.* at 11. The discharge diagnosis was panic disorder. *Id.* at 13. No medical records beyond the spring of 2014 have been filed, although Ms. Combs alleges that she continues to “have problems and experience more syncopal episodes at a rate of approximately once per week,” and that generally “she still constantly feels unwell, unhealthy, and does not know exactly when one of

⁶ Ativan is the trademark name for Lorazepam. *Dorland’s* at 173. Lorazepam is used to treat anxiety disorders, including depression. *Lorazepam (Oral Route)*, Mayo Clinic, <https://www.mayoclinic.org/drugs-supplements/lorazepam-oral-route/description/drg-20072296> (last accessed on Feb. 2, 2018).

these fainting episodes will occur.” See Petitioner’s Prehearing Submission, dated Apr. 20, 2017 (ECF No. 39) at 7.

II. Witness Testimony

A. Mrs. Jenny Howard

Mrs. Howard was the only fact witness to testify in this action. See Tr. at 5-55. She generally testified about reactions Petitioner allegedly had to her HPV doses that were not captured in the medical record.

She recalled Ms. Combs to be very healthy and active before receiving the first dose of the vaccine, but then experiencing an immediate reaction, although Mrs. Howard did not realize at the time it had anything to do with the vaccine. *Id.* at 14-15, 27. In so testifying, she acknowledged that her statements were inconsistent with her witness statement, which identified reactions as beginning only after the *second* dose (Ex. 1 (ECF No. 6-1) at ¶ 3) – but she attempted to explain the discrepancy, stating that she meant only that Petitioner’s dizziness or fainting began after the second dose in February 2012. *Id.* at 9-11, 35. Mrs. Howard did not, however, realize the significance of such symptoms at the time, and therefore did not seek medical treatment for her daughter. *Id.* at 11-12.

Mrs. Howard was asked questions about Petitioner’s March 2012 fall in their backyard. She described the backyard as featuring many “banks and hills” that Petitioner enjoyed climbing. Tr. at 50. Ms. Combs fell from a “pretty steep” embankment, rolling down the hill. *Id.* at 50-51, 53. She acknowledged that Petitioner arrived at the hospital before her, and therefore gave an initial history to treaters (which says nothing about dizziness as precipitating the fall). *Id.* at 36. However, Mrs. Howard insisted that dizziness was the cause of the Petitioner’s fall regardless of what the records set forth. *Id.* at 37-38. She added that her supplemental witness statement (Ex. 13 (ECF No. 20-1)) confirmed a discussion she had with Ms. Combs, in which Petitioner told her that dizziness preceded the fall (although, because this instance of dizziness occurred before Petitioner began feeling faint as often as she did later, Mrs. Howard did not realize it was related to her daughter’s later symptoms). *Id.* at 38-39.⁷

Thereafter, Mrs. Howard stated, Ms. Combs began feeling worse and worse, such that by the end of 2012 she was regularly missing school and no longer felt like participating in activities she used to enjoy. Tr. at 13-14. Petitioner also began passing out after dizzy spells, with the first

⁷ As noted, Ms. Combs did not testify in the hearing (nor did she file a witness statement (Tr. at 33-34)), leaving only Mrs. Howard to relate what was told to her. Although it is well understood that virtually any kind of evidence is admissible in a Program case, and will therefore be considered by a special master in determining if an entitlement award is appropriate, the hearsay character of what Petitioner purportedly told Mrs. Howard is self-evident. As a result, I give such statements little evidentiary weight.

instance of fainting occurring while at her job at McDonalds in the summer of 2012. Tr. at 15-16. Often the feeling that Ms. Combs was going to faint preceded, but did not always lead to, fainting. *Id.* at 40-42. These episodes would occur in many different places – at Ms. Combs’s work, in the shower, etc. *Id.* at 19-20. Although Petitioner was treated after her episode that summer, Mrs. Howard acknowledged that she did not seek greater medical evaluation for her daughter at the time (although she now wishes she had), and that nothing was identified as wrong after Ms. Combs was treated for the June 2012 incident. *Id.* at 17.

Mrs. Howard represented that she was concerned by the time of the third HPV vaccine dose (September 2012) about the possible side effects of the vaccine, based upon research she had done on her own, but that Ms. Combs wanted to receive it because her school nurse was providing store gift cards to individuals who completed the three-dose course. Tr. at 18. Not long thereafter, Ms. Combs experienced her second work incident in November 2012 that resulted in her CHH hospitalization. *Id.* at 20-21. From this point on, Ms. Combs became “progressively worse,” and would usually experience some pre-syncope symptoms before actually passing out. *Id.* at 22-23. It was around this time that Ms. Combs was diagnosed with vasovagal syncope – as Mrs. Howard admitted, the most consistently-provided explanation for her symptoms (other than hypoglycemia). *Id.* at 21, 46-47. Ms. Combs continues today to experience symptoms similar to what she displayed at that time, although in Mrs. Howard’s estimation “it’s not as bad” as it was originally. *Id.* at 25.

On cross examination, Mrs. Howard provided some additional details about her daughter’s treatment and condition. She acknowledged that Ms. Combs had struggled with anxiety and other mental health issues before receiving any of the HPV vaccine doses, although she denied hearing from Ms. Combs or any treaters that her syncope symptoms could have been caused by such problems. Tr. at 29, 47-48. She also noted that some treaters, as early as the November 2012 hospitalization, had proposed that Ms. Combs undergo a “tilt table” test⁸ often used to evaluate an individual’s orthostatic tolerance, but it was not performed. *Id.* at 54-55. And she took issue with contemporaneous medical records that did not record the extent of symptoms she now alleges Ms. Combs experienced after her first and second HPV doses, claiming that she attempted to inform treaters of what she had seen but that they had not recorded her statements (and were otherwise not aware of what she witnessed firsthand at home). *Id.* at 31, 34, 43.

⁸ A tilt table test is used to evaluate syncope by measuring heart rate and blood pressure in response to the body’s change in position. *Tilt Table Test*, Mayo Clinic, <https://www.mayoclinic.org/tests-procedures/tilt-table-test/about/pac-20395124> (last accessed Feb. 8, 2018). During the test, the patient begins by lying flat on a table for around 15 minutes. *Id.* The table is then quickly tilted upright to change the body’s position from lying down to standing up. *Id.* The table generally remains upright for 45 minutes to allow the doctor to monitor the patient’s cardiovascular response. *Id.*

B. *Dr. Patrick Nemechek*

Dr. Nemechek, Petitioner's sole expert witness, filed two expert reports in this case and testified at hearing. *See* Expert Report, dated Sept. 22, 2015, filed as Ex. 14 (ECF No. 23-1) ("First Nemechek Rep."); Expert Report, dated Jan. 29, 2016, filed as Ex. 73 (ECF No. 32-1) ("Second Nemechek Rep."); Tr. at 56-158. He provided the opinion that Ms. Combs's syncope was the result of autonomic damage caused by her receipt of the HPV vaccine.

In cross examination, Respondent raised threshold questions about whether Dr. Nemechek possessed the expertise necessary to provide a reliable expert opinion in this case. Dr. Nemechek is an osteopath (educated at the Kansas City University of Health Sciences in Kansas City, Missouri), has never held board certification in immunology, neurology, or the sub-specialty of the autonomic nervous system, and has no experience conducting research into some of the matters his opinion touched upon, such as the function of cytokines in the immune system. *See generally* Nemechek CV, filed as Ex. 15 (ECF No. 23-2); Tr. at 94-95, 154. He is in fact not board certified in *any* particular specialty at all at the moment (although he was previously board certified in internal medicine). *Id.* at 59. He also cited numerous publications in his CV, some of which he represented dealt with immune system dysfunction. *Id.* at 61. In fact, close inspection of the listed publications revealed them to largely consist of abstracts, articles he reviewed pre-publication but for which he did not serve as a primary author, letters to the editor of journals, or items not actually published in a peer-reviewed publication. *Id.* at 96-110. He maintained that he received specialized training in the study and treatment of autonomic problems in Portugal in 2010, but could not provide any details as to the course taken or individuals or institutions responsible for the course. *Id.* at 110-12.

Instead, Dr. Nemechek relied almost wholly on his own experience in his present clinical practice – and in particular on his efforts to treat problems attributed to autonomic dysfunction – for his views on the neurologic and immunologic matters in contention. Tr. at 61-64, 110, 153-54. Dr. Nemechek currently works in Arizona⁹, where he operates "Nemechek Autonomic Medicine," a medical practice aimed at treating autonomic dysfunction, which (as its website indicates) is purported to be "present in most all chronic diseases."¹⁰ *See* Tr. at 62-64. As pointed out on cross examination, Dr. Nemechek's website asserts that he has developed a "protocol" for reversing brain inflammation that, in turn, can successfully treat autonomic damage. *Id.* at 141. The protocol

⁹ Before relocating to Arizona, Dr. Nemechek had practiced medicine in Kansas, where for a time he focused on assisting individuals with weight loss. Tr. at 115-17. At some point in that prior timeframe, Dr. Nemechek received a warning from the Food and Drug Administration regarding the adequacy of certain of his study parameters. *Id.* at 113-14.

¹⁰ *See Autonomic Disorders*, Nemechek Autonomic Medicine, <https://www.nemechekconsultativemedicine.com/disorders/> (last accessed on Feb. 2, 2018).

is claimed to have been effective in the treatment of Alzheimer’s disease¹¹ and seizure thresholds, and has also been deemed to be helpful in individuals with autism (*Id.* at 142) – although Dr. Nemechek admitted that the protocol lacks reliable clinical support, and has never been the subject of any peer-reviewed publications. *Id.* at 143.

Dr. Nemechek’s opinion began with an overview of the autonomic nervous system and its relevance to Ms. Combs’s alleged vaccine injury. *See generally* First Nemechek Rep. at 3-4. As Dr. Nemechek explained, the autonomic system is responsible for the “coordination and regulation” of organ function, metabolism, and other “background” body functions that occur without conscious intent. *Id.* at 3; Tr. at 66-67. One of its branches, the sympathetic nervous system, functions as a “complete controlling mechanism” for immune system function and inflammation. Tr. at 67. Autonomic dysfunction, or “dysautonomia,” includes orthostatic intolerance, which he defined as the “inability to maintain proper blood pressure in your head when you’re standing upright.” *Id.* at 68. Damage to the sympathetic nerve system, attributable to a lack of “proper sympathetic inputs,” can result in this kind of dysautonomia as well as other symptoms. *Id.* at 69. Dr. Nemechek made clear that his opinion is that Ms. Combs experienced autonomic system *damage* as a result of the HPV vaccines, and not merely that the vaccines caused autonomic dysfunction. *Id.* at 118.

One condition Dr. Nemechek deemed particularly relevant to his theory herein was hypoglycemia, which he defined as a suboptimal blood sugar level. Tr. at 70. The autonomic system helps regulate blood sugar levels, reacting with a variety of symptoms (e.g., sweating and tachycardia) in the form of a “sympathetic discharge” if levels are driven too low. *Id.* at 71. Accordingly, the sympathetic nervous system provides a “defense mechanism” to prevent hypoglycemia. *Id.* at 71-72. Hypoglycemia can be dangerous – especially “neuroglycopenia,” which Dr. Nemechek defined as lacking sufficient blood sugar levels in the brain to maintain proper brain function, and which can result in a loss of consciousness. *Id.* at 77.

Dr. Nemechek then turned to the role a vaccine could play in causing dysautonomia. In his view, vaccines have the capability of damaging the autonomic system, and can do so in different ways. For example, a vaccine can induce an autoimmune reaction, by “triggering the production of autoantibodies” that attack self structures. First Nemechek Rep. at 3; Tr. at 78. Alternatively, cytokines (which Dr. Nemechek defined as chemicals produced by the immune system in response to infection or injury that serve a “critical role in coordinating the body’s defensive [immune] system”) can “surge” in production after stimulation by a vaccine, thereby causing injury. First Nemechek Rep. at 7; Tr. at 78. Such an overproduction of cytokines could thereafter become chronic, when microglia – non-neuronal glial cells in the brain that also play an immune defense

¹¹ Alzheimer’s disease is categorized as a progressive central neurodegenerative disorder. *Dorland’s* at 528. The first signs of Alzheimer’s disease include slight memory loss and personality changes, but these typically progress into profound dementia in five to ten years. *Id.*

role – are primed to become an excess source of cytokine production, often as a result of some prior insult (e.g., stress or a concussion). Tr. at 78, 140-41.

The receipt of multiple doses of HPV vaccines, Dr. Nemechek maintained, could amount to an “immunological concussion” sufficient to prime such microglia. Once an individual had microglia primed to produce cytokines, recovery from the initial insult would be thwarted, resulting in “continual leakage of cytokines in the brain,” and a “growing level of . . . sympathetic damage.” Tr. at 90-91. Thus, the ongoing primed microglia would encourage “persistent inflammation” in the brain, worsening with each subsequent dose of HPV vaccine, until after the third, when hypoglycemia could result from a person’s now-damaged autonomic nervous system, resulting in syncope. *Id.* at 92-93. A “pattern of increasing symptomology” with each HPV dose would, Dr. Nemechek opined, stand as strong evidence that microglial priming was in fact occurring. *Id.* at 157.

To support his contention that “the development of cumulative brain injury from a vaccine-induced inflammatory insult is now a proven fact” (Second Nemechek Rep. at 2), Dr. Nemechek cited a single article, C. Cunningham, *Microglia and Neurodegeneration: The Role of Systemic Inflammation*, 61 *Glia* 71 (2013), filed as Ex. 74 (ECF No. 32-2) (“Cunningham”). Tr. at 84. Cunningham is a review article that (through reference to other studies) considers how “systemic inflammation negatively impacts on chronic neurodegenerative disease,” such as Alzheimer’s disease, Parkinson’s disease, or amyotrophic lateral sclerosis. Cunningham at 72, 78. It does not discuss how a vaccine might prime microglia, however, to produce cytokines in a chronic fashion. Dr. Nemechek also referenced case reports involving the disease rheumatoid arthritis, and a drug that helped patients improve their autonomic function by blocking a particular cytokine, in order to corroborate the argument that cytokine overproduction could be pathologic. Tr. at 79.

Dr. Nemechek acknowledged that he could point to no literature that would establish *how* a vaccine would initiate a chronic cytokine production process capable of causing injury akin to what Petitioner has experienced. Tr. at 154. Nevertheless, he did attempt to offer some literature involving the HPV vaccine that he maintained supported the conclusion that the HPV vaccine had the potential to cause “changes reflective of abnormal function” in the autonomic nervous system. *Id.* at 130. In particular, he relied on an article discussing 40 instances of reported neurologic symptoms in Japanese girls who received the HPV vaccine between mid-2013 and the first quarter of 2014. Tr. at 148; T. Kinoshita et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization with the Human Papillomavirus Vaccine*, 53 *Intern. Med* 2185 (2014), filed as Ex. 22 (ECF No. 24-7) (“Kinoshita”). Of the 40 subjects in Kinoshita, eight met diagnostic criteria for orthostatic intolerance, while four met the clinical standard for postural orthostatic tachycardia syndrome (“POTS”). Kinoshita at 2193, 2198. On cross examination, however, Dr. Nemechek admitted that (in addition to involving disorders that Petitioner did not have) the association Kinoshita proposed between the HPV vaccine and injuries involving the

sympathetic nerve system, like POTS, has been called into question. Tr. at 131-32.¹²

Dr. Nemechek similarly cited an article co-authored by Dr. Mark Geier (D. Geier and M. Geier, *A Case-Control Study of Quadrivalent Human Papillomavirus Vaccine-Associated Autoimmune Adverse Events*, 34 Clin. Rheumatology 1225 (2015), filed as Ex. 46 (ECF No. 27-1)) – an individual whose qualifications to provide expert testimony in Vaccine Program cases have been consistently rejected in numerous published decisions. Tr. at 134-36; *see also King v. Sec’y of Health & Human Servs.*, No. 03-584V, 2010 WL 5470787, at *10 (Fed. Cl. Spec. Mstr. Dec. 13, 2010) (“[i]n many cases, stretching over many years, special masters or judges of this court have offered negative comments on the credibility, credentials, honesty, or other aspects of the testimony or opinions of Dr. Mark Geier”).

Relying upon the above, Dr. Nemechek reviewed Ms. Combs’s record to illustrate how his theory applied to her circumstances. He asserted that there was nothing in her record before the first HPV vaccination to suggest she suffered from any form of orthostatic intolerance or syncope (thereby allowing the inference that the vaccine was a factor in its subsequent development). Tr. at 82. He deemed Mrs. Howard’s testimony of worsening after the second HPV dose significant, since that evidenced recurrent microglial priming due to additional exposure to the vaccine, producing injury that could not heal. *Id.* at 84. He also pointed to Petitioner’s June 2012 orthostatic test results, which (among other things) revealed heart palpitations significant enough in rate increase from sitting to standing to be considered abnormal – and even evidence of POTS. *Id.* at 87 (referencing Ex. 6 at 55). Tachycardia could, he proposed, establish that Ms. Combs had experienced underlying autonomic harm. Tr. at 92. And he emphasized that Ms. Combs’s purported “polycystic ovarian syndrome” (PCOS)¹³ was understood to precipitate insulin regulation problems that could contribute to hypoglycemia. *Id.* at 76.

Dr. Nemechek’s theory did not embrace the diagnosis of vasovagal syncope that Petitioner’s physicians reached after treating her, and he expressly denied it could explain her symptoms. Tr. at 124. He agreed that an individual could experience vasovagal syncope without

¹² Respondent’s expert, Dr. Low, specifically took issue with Kinoshita as supporting a connection between HPV and autonomic conditions like POTS, stating that subsequent evaluation of its data by European medical institutions revealed that the supposed correlation between vaccination and the onset of such injuries could be attributed more to the age of onset of the subjects rather than time of vaccination, and that the incidence rates of such conditions were no different than what would be expected for all girls in the relevant age groups – thereby suggesting that any increase was merely a statistical artifact attributable to “overreporting” rather than establishing a significant and reliable association. Tr. at 210-11.

¹³ Polycystic Ovarian Syndrome is a hormonal disorder common in young women of reproductive age, causing the ovaries to develop small fluid-filled follicles. Symptoms include irregular periods, excess androgen (male hormone), and polycystic ovaries. The cause is unknown, but long-term complications can include type 2 diabetes and heart disease. *Polycystic Ovary Syndrome (PCOS)*, Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/pcos/symptoms-causes/syc-20353439> (last accessed on Feb. 2, 2018). Ms. Combs’s medical records suggest that she was diagnosed with PCOS in early September 2012. Ex. 2 at 7-8.

also suffering from autonomic damage, although he also maintained that such damage could cause it as well. Tr. at 125-26 (citing E. Lambert et al., *Sympathetic Dysfunction in Vasovagal Syncope and the Postural Orthostatic Tachycardia Syndrome*, 5 *Frontier in Physiology* 1 (2014), filed as Ex 75 (ECF No. 32-3)). Indeed, Dr. Nemechek acknowledged that there were many possible causes for vasovagal syncope apart from damage to the autonomic system. Tr. at 127-29.

Dr. Nemechek also opined that the timeframe in which Ms. Combs developed syncope was medically acceptable. He attributed some of her overall course (in which she allegedly began exhibiting pre-syncope symptoms in March 2012, a month after the second HPV dose, but then experienced them in an up-down pattern over the next several months) to the “unique feature of this microglia priming phenomenon,” which became self-perpetuating as chronic cytokine production began. Tr. at 81-82. But Ms. Combs may reasonably have not realized at first that her earliest symptoms (for example, the purported dizziness that resulted in her March 2012 fall) were serious. *Id.* at 144. Ultimately, he generally referenced Cunningham as supporting the reasonableness of the timeframe, stating it could possibly support the initiation of neurologic damage beginning as soon as a week after vaccination. *Id.* at 145-47.

On cross-examination, Dr. Nemechek acknowledged reliability problems with the part of his theory that identified microglial activation as a source of Petitioner’s alleged autonomic damage. He agreed that there was no test that existed to establish microglial activation was occurring at all, and that Petitioner’s treaters had never performed any testing that might indirectly or directly confirm this. Tr. at 137-38, 156. He also admitted to holding the belief that a wide variety of instigating factors that individuals regularly encounter could just as likely cause microglial activation as a vaccine. For example, a diet deficient in omega-3 fatty acids¹⁴ could result in such activation, and could also be treated with a diet including a different kind of oil that, while not capable of reversing activation, could at least be “protective” against the purported inflammation that the activation purportedly encourages. Tr. at 139.

Dr. Nemechek was also unable to deny that his theory had larger deficiencies. Thus, he could not specifically identify where in Petitioner’s body the alleged sympathetic damage being caused as a result of the HPV vaccine was occurring (although a charitable reading of his theory would place it as initiating in the brain). Tr. at 126-27. He could point to no independent, corroborative evidence that Ms. Combs’s symptoms were the product of cytokine overproduction, such as inflammation. *Id.* at 158. He also noted the circularity of his theory, which relied on objective evidence of orthostatic intolerance (for example, the blood pressure and pulse readings taken for Ms. Combs in June 2012) to establish the autonomic damage he was alleging to have

¹⁴ Omega-3 fatty acids are a category of fats necessary for body cells to properly function. The most common (and crucial) omega-3 fatty acids are eicosapentaenoic (EPA) and docosahexaenoic (DHA). Omega-3 fatty acids are typically found in oily fish, such as salmon, tuna, and trout. *What Are Omega-3 Fatty Acids From Fish Oil?*, Mayo Clinic, <https://www.mayoclinic.org/what-are-omega-3-fatty-acids-from-fish-oil/art-20232583> (last accessed Feb. 2, 2018).

occurred – even though he simultaneously admitted that such orthostatic results could be obtained for a person with a functioning, undamaged autonomic nervous system. Tr. at 119-20, 122. And he allowed that, although his theory seemed to propose that hypoglycemia in the brain explained most of Ms. Combs’s syncopal events, she had not been consistently shown to be hypoglycemic in each episode. Tr. at 123.

C. *Dr. Phillip Low*

Dr. Low offered a single expert report in this case and testified at the hearing. *See* Expert Report, dated Dec. 16, 2015, filed as Ex. A (ECF No. 31-1).

In contrast to the many reasonable points raised by Respondent about the credentials of Petitioner’s expert, Dr. Low’s background and medical/scientific qualifications were significantly more impressive and trustworthy. *See generally* Tr. at 160-72. Dr. Low received his medical and research doctorate degrees from the University of Sydney in Sydney, Australia. *See* Low CV, filed as Ex. B (ECF No. 31-10) (“Low CV”). Following graduation, Dr. Low completed a fellowship in internal medicine with the Royal Australian College of Physicians. Tr. at 161. Currently, Dr. Low serves as a Professor of Neurology at the Mayo Clinic Medical School. Low CV at 4.

During his time with the Mayo Clinic, Dr. Low has served in various departmental and academic capacities, including Director of the Neuroscience Laboratory, Director of the Autonomic Reflex Laboratory, and Chairman of the Division of Clinical Neurophysiology. Low CV at 3-4. At Mayo, he founded the autonomic reflex lab, which focuses on the clinical aspects of the nerve micro-environment (including the blood nerve barrier, nerve oxygenation, glucose, and endoneurial fluid pressure and contents). Tr. at 164. Dr. Low has co-authored over 400 items of literature in the field of autoimmunity, including the largest series of publications centered on antibody-mediated autoimmune neuropathies. *Id.* at 170-71; *see also* Low CV at 10-51. Dr. Low has also published on the role of cytokine autonomic issues. Tr. at 171. He has served on the editorial boards of multiple journals centered on autonomic and nervous system research, including the *Journal of Clinical Neurophysiology*. Low CV at 5. He also consistently serves as a research advisor to postdoctoral fellows at the Mayo Clinic Medical School. *Id.* at 7-9.

Over the past forty years, Dr. Low’s time has been divided evenly between patient practice and research. Tr. at 167. During his clinical practice (focused on autonomic disorders), Dr. Low estimated, he sees thirty patients per week in a supervisory role and five patients on a more intensive basis. *Id.* He has diagnosed “thousands” of patients with autonomic disorders and autoimmune neuropathies. *Id.* at 167-68. Dr. Low also stated that he has treated patients with reflex syncope. *Id.* at 168. Dr. Low was thus amply qualified to provide expert testimony in this case

useful to its resolution.¹⁵

Like Dr. Nemechek, Dr. Low began his testimony with an overview of some of the medical terms and concepts relevant herein. Dr. Low deemed the autonomic nervous system “neurovegetative,” meaning that it “functions in the background” of the central nervous system. Tr. at 172-73. He took pains to distinguish between autonomic failure and dysfunction, deeming the former attributable to some serious structural nerve system failure. *Id.* at 173-74. Dr. Low acknowledged that diseases can cause autonomic damage – but in such cases the damage would be testable and corroborated by multiple pieces of evidence of symptomology. *Id.* at 243-44. He cited autonomic neuropathy, such as a neuropathy caused by diabetes, as an example of such a disease capable of harming the autonomic system. *Id.* at 174, 245. When a person has a diabetic neuropathy, she will often experience a wide variety of concurrent symptoms affecting many disparate organ systems, such as hypotension, bladder dysfunction, erectile dysfunction, and gastroparesis.¹⁶ Very often, the disease causing autonomic failure will predate the symptoms resulting from autonomic damage. *Id.* at 245. Testing exists to measure whether the autonomic nervous system has been damaged, and to pinpoint the structures at issue. *Id.* at 176-77.

Autonomic dysfunction, by contrast, is inherently less serious. It can simply reflect a normal or expected autonomic reaction (for example, feeling dizzy or faint after missing a meal) that is not indicative of greater autonomic failure. Tr. at 178, 227. As a result, Dr. Low views the term “dysautonomia” to be a “terrible” and imprecise term to describe autonomic problems that cannot be attributed to identifiable autonomic failure. *Id.* at 173.

Dr. Low also discussed several kinds of autonomic dysfunction relevant to the claim herein. In his understanding, orthostatic intolerance (meaning in essence that a person feels different when she stands up) can be caused by many different things, but is not necessarily indicative of autonomic failure, and in fact can exist without such failure. Tr. at 176, 215-16. Dr. Low deemed reflex syncope a “type” of orthostatic intolerance commonly presenting in a person’s teen years. *Id.* at 181-82. It is characterized by sudden blood pressure drops due to “a switching off of the

¹⁵ I acknowledge that Dr. Low has less overall experience and background in immunology than autonomic-related matters – although Dr. Nemechek’s expertise in immunology is no better (if not substantially worse). But since the Petitioner bears the burden of proof in this case, the fact that neither expert has the kind of credentials to opine on immunologic topics that I would prefer in other cases cuts only against Petitioner and not Respondent. *See Dean v. Sec’y of Health & Human Servs.*, No. 13-808, 2017 WL 2926605, at *15-16 (Fed. Cl. Spec. Mstr. June 9, 2017).

¹⁶ Gastroparesis is a condition characterized by “delayed gastric emptying,” thus causing digestive interference. *See Morgan v. Sec’y of Health & Human Servs.*, No. 12-77V, 2017 WL 6893079, at *10 (Fed. Cl. Spec. Mstr. Dec. 6, 2017). The condition affects the normal movement of muscles in the stomach, resulting in slower motility and difficulty emptying the stomach. Symptoms can include nausea, vomiting, digestive problems, and nutrition problems. *Gastroparesis*, Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787> (last accessed on Feb. 2, 2018).

sympathetic efferents,”¹⁷ often triggered by a sympathetic surge. *Id.* at 177, 213. Hypoglycemia can also trigger a sympathetic surge resulting in syncope, but is not itself evidence of structural damage to the autonomic system, especially given how reversible it is (as eating can readily raise blood sugar levels). *Id.* at 178-80. By contrast, neuroglycemia (reduced glucose in the brain) is a slowly-developing process, and is characterized by extreme symptoms, like coma, that result from exceedingly low blood sugar levels not comparable to hypoglycemia, which can be abrupt. *Id.* at 181.

Dr. Low offered the opinion that Petitioner’s symptoms were best characterized as reflex/vasovagal syncope (the etiology of which is unknown), with no evidence in the medical record of true damage to the autonomic nervous system. Tr. at 172, 205, 221, 244. Referencing the consensus statement on the recognized clinical features of syncope (Ex. G), Dr. Low opined that Ms. Combs’s presentation included them, such as the abrupt, “premonitory symptoms” of orthostatic intolerance and the short duration of episodes in which she was unconscious. Tr. at 185. Her frequently slow relative heart rate was further corroboration of the accuracy of the syncope diagnosis. *Id.* at 183. In fact, the symptoms she experienced reflected a *strong* sympathetic response, and hence refuted Dr. Nemechek’s conclusion that her autonomic system had been damaged. *Id.* at 184 (having studied “thousands of patients with syncope” in part “to sort out who has autonomic failure and who has not,” evidence of strong autonomic reactions makes one “darn sure” that “the sympathetic is intact”), 223. And her overall pattern of syncope events was not evidence to Dr. Low of autonomic nervous system injury. *Id.* at 218.

To support his opinion, Dr. Low engaged in a detailed walkthrough of Ms. Combs’s medical records. He deemed the symptoms reported from her June 2012 syncopal event to constitute “compelling” evidence of “prominent sympathetic activity.” Tr. at 186, 236. He particularly took note of her blood pressure readings, which showed a modest systolic drop, coupled with a “dramatic increase” in diastolic pressure, attributing this to “intense vasoconstriction” and therefore proof of a functioning sympathetic nerve system. *Id.* at 187¹⁸ At that time, her glucose levels were also normal, discounting hypoglycemia as a cause. *Id.* at 188. The November 2012 records were consistent, although Dr. Low acknowledged they did reveal moderate hypoglycemia (although he noted this could have been a transient occurrence and not evidence, as Petitioner argues, of a chronic condition originating in the brain). *Id.* at 189, 191.

¹⁷ A sympathetic efferent is a motor nerve that carries impulses from the central nervous system toward the periphery. *Dorland’s* at 1252.

¹⁸ Systolic pressure is produced by the systole, or contraction of the heart by which blood is forced into the aorta. *Dorland’s* at 1865. Diastolic pressure is produced during the heart’s dilation period, or interval between the second and first heart sounds. *Id.* at 511. The American Heart Association defines systolic pressures as the amount of pressure your blood exerts against the artery wall when the heart beats. Diastolic pressure, in turn, is defined as the amount of pressure exerted against the artery wall when the heart is resting between beats. *Understanding Blood Pressure Readings*, Am. Heart. Assoc., http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/Know/Your/Numbers/Understanding-Blood-Pressure-Readings_UCM_301764_Article.jsp#.WnzIV2eWyUk (last accessed Feb. 8, 2018).

Dr. Low commented extensively on the records generated during Ms. Combs's November 2012 hospital stay. The CHH neurologic consult she obtained at this time revealed a history provided to treaters that Dr. Low deemed a "nice description of sympathetic activation," rather than evidence of autonomic structural damage. Tr. at 190. He similarly characterized the notation that during her EEG, Ms. Combs was pale, hyperventilating, and displaying an increased heart rate (*see* Ex. 9 at 12) as proof of a functional "sympathetic burst." *Id.* at 191-92. The cardiology consult she received (Ex. 9 at 15) was also consistent with reflex syncope, while not reflecting a dangerous hypoglycemic reaction, which would entail far more "frightening" symptoms (very low glucose readings, a comatose patient, etc.). *Id.* at 193. He thus found the cardiologist's diagnosis (vasovagal syncope) accurate, along with his treatment advice that she increase fluid intake and avoid caffeine. *Id.* at 194. Dr. Low pointed out other record instances from this time period which were consistent with his interpretation of the proper diagnosis. *Id.* at 196-97, discussing Ex. 9 at 148-49.

Records from treatment Ms. Combs received in 2013 were in Dr. Low's view also reflective of a person suffering from reflex syncope rather than autonomic damage. As the June 2013 records demonstrated, Petitioner's pre-syncopal feelings of lightheadedness constituted the "gray area" before syncope that Dr. Low understands to be indicative of a healthy rather than damaged autonomic system. Tr. at 199. Her June 12, 2013 orthostatic readings (Ex. 8 at 130) showed a heart rate increase but normal blood pressure – evidencing some tachycardia but not enough to find that her sympathetic system was injured. Tr. at 200. Dr. Low was also asked to compare orthostatic readings taken three separate times between June 2012 and June 2013. Tr. at 202-03, referencing Ex. 6 at 55, Ex. 9 at 149, and Ex. 8 at 130. He noted that the tachycardia levels were "all over the place," with some normal and some not, suggesting to him that the "trigger" for syncope was less likely caused by structural harm to the autonomic nervous system than by differences in Ms. Combs's management of factors within her control. Tr. at 203. He reiterated his earlier point that true autonomic failure would not be evidenced, as here, by increases in diastolic pressure. *Id.*

In commenting on the medical records, Dr. Low proposed several alternative explanations for Ms. Combs's syncope. Deconditioning, or the physiological response to decreased activity, is a "powerful trigger" for syncope caused by sympathetic overactivity, and Dr. Low found evidence of deconditioning in aspects of the record. *See, e.g.*, Tr. at 195 (citing Ex. 9 at 43), 218-19. He also identified stress and anxiety as plausible explanations. *Id.* at 202 (citing Ex. 7 at 52). Even an instance in which Ms. Combs reported syncopal symptoms after a hot shower provided a credible explanation, because the heat from the water could cause vasodilation leading to a blood pressure decrease. *Id.* at 200-01 And Dr. Low placed all of the above in the overall context of Petitioner's age, noting that a young person might in fact experience symptoms like those complained of in this case and not even meet the actual clinical criteria for syncope at all. *Id.* at 204.

Dr. Low did not find Petitioner’s causation theory persuasive. As he noted, that theory was heavily dependent on the finding that Ms. Combs’s syncope was the product of autoimmune damage to the autonomic nervous system, resulting in hypoglycemia-instigated losses of consciousness – a theory that in his view “doesn’t make any sense.” Tr. at 205-06. In so opining, he emphasized the overall lack of correlation in the medical records of hypoglycemia of the severity necessary to produce a loss of consciousness. *Id.* at 205. Indeed, Dr. Low observed instances in which the Petitioner experienced syncopal events *without* any evidence of preceding hypoglycemia. *Id.* at 228. Had low glucose been the cause of her syncope, Dr. Low would also have expected evidence of neurologic deficits or seizure¹⁹ – all absent in Ms. Combs’s case. *Id.* at 228.

Besides criticizing the extent to which Petitioner’s theory did not match the record, Dr. Low contested Dr. Nemechek’s assertion that a component mechanism of her injury was attributable to microglial activation resulting in chronic cytokine production. He noted that he has in fact been studying an uncommon disease involving microglial activation, and hence has first-hand awareness of the concept. Tr. at 206-07. But in his experience, except in rare circumstances microglial activation was more commonly a transient rather than chronic occurrence. *Id.* Dr. Low was unaware of any research or literature supporting the contention that a vaccine can cause microglial activation sufficient to harm the autonomic nervous system via cytokine production,²⁰ and he characterized the embracing of such an argument as reflecting a “lack of understanding of an important part of the nervous system.” *Id.* at 207. When asked whether Cunningham supported this component of Petitioner’s theory, Dr. Low demurred, pointing out that the article addressed known, extremely serious neurodegenerative disorders, like Alzheimer’s, with a “clear hypothesis about the mechanism of microglial activation,” whereas here there was no evidence of a “progressive process,” just repeated occurrences of syncope. *Id.* at 208, 246-47.

Dr. Low also disputed the reliability of theorizing that the HPV vaccine could instigate syncopal symptoms akin to what Ms. Combs experienced via an autoimmune process caused by the mechanism of molecular mimicry. In so doing, he took issue with the contention that POTS stood as an example of an autoimmune-caused kind of orthostatic intolerance. Tr. at 209-10. He termed such a theory “loose thinking,” and referenced an item of literature filed by Petitioner that

¹⁹ Dr. Low acknowledged an instance from the medical records in which it appeared that Petitioner had displayed reported abnormal movements in connection with a loss of consciousness, but dismissed its significance, observing that true seizure activity for Ms. Combs had not been confirmed on an EEG, and that in any event “normal people can have syncopal episodes and have a few jerks” without it being deemed proof of a seizure. Tr. at 229.

²⁰ Dr. Low was also dismissive of the component of Petitioner’s theory relying on cytokines as mediators of autonomic damage, noting that in his view “there’s a lot of nonsense spoken about cytokines” based on a lack of “meaningful” data about the role they actually play in an autoimmune process, especially since cytokines are released by the body in response to wide variety of stimuli. Tr. at 171; *see also* 247-48 (characterizing theories dependent on cytokines as causing aberrant immunologic responses as “very loose,” and “something that’s often evoked when you don’t get a better explanation” from a comprehensive look at a disease process).

Dr. Low had actually co-authored, M. Thieben, et al., *Postural Orthostatic Tachycardia Syndrome: The Mayo Clinic Experience*, 82 Mayo Clin. Proc., 308 (2007), filed as Ex. 71 (ECF No. 29-6) (“Thieben”). As Thieben indicated, Dr. Low’s own research at the Mayo Clinic had initially identified an antibody that arguably was evidence of an autoimmune basis for POTS (Thieben at 311-12), but Dr. Low’s group had subsequently determined that there was “no correlation” with autonomic injury and the identified antibody, leading the Mayo researchers to recommend that others not test for the antibody since to do so was a “waste of time and effort.” Tr. at 210; *see also* Tr. at 249 (after looking at “many more cases,” and “the association between antibody titer and the course of illness,” no association was found to suggest POTS was autoimmune in nature).

On cross examination, Dr. Low was asked about the evidence in the record suggesting that Petitioner’s symptoms had worsened in correlation to the HPV doses she received over time, but maintained that this did not reflect “challenge/re-challenge”²¹ evidence that subsequent doses were causing swifter and more severe reactions. Tr. at 224. For re-challenge to be evident, Dr. Low maintained, there would need to be “highly specific” proof of a heightened and more robust immune response, such as biomarkers understood to be associated with the vaccine at issue. *Id.* He would also have expected to see proof of progressive damage to Ms. Combs’s autonomic system, when *no* such evidence was seen at all in this record. *Id.* at 225-26. Dr. Low also denied that the vasovagal/reflex syncope diagnosis was undercut by record instances in which the Petitioner’s heart rate raced rather than was slow, agreeing that a low rate was more consistent with the diagnosis, but that an increased rate was also consistent with sympathetic overactivity (which precedes syncope), and that such readings did not otherwise suggest to him the diagnosis was incorrect. *Id.* at 230-32.

III. Procedural History

As stated above, this case was initiated in September 2014. After several months of medical records gathering and filing, Respondent filed his Rule 4(c) Report in April 2015 (ECF No. 17), recommending against an entitlement award. In September 2015, Ms. Combs filed Dr. Nemechek’s first expert report and numerous items of medical literature in support, and in response Dr. Low’s report was filed by Respondent in December of that same year. Petitioner filed a rebuttal report from Dr. Nemechek in January 2016, and then (after the parties determined that settlement was not possible), August 1, 2017 was agreed to as the date for the entitlement hearing

²¹ Challenge/re-challenge is “a paradigm for exploring whether one substance caused an adverse reaction. Under this model, an individual who has had an adverse reaction to an initial vaccine dose (the challenge event) suffers a worsening of symptoms after a second or third injection (the re-challenge event.)” *Viscontini v. Sec’y of Health & Human Servs.*, No. 98-619V, 2011 WL 5842577, at *22 (Fed. Cl. Spec. Mstr. Oct. 21, 2011) (quoting *Doe/70 v. Sec’y of Health & Human Servs.*, 95 Fed. Cl. 598, 603 (2010) (quotations omitted)), *mot. for review den’d*, 103 Fed. Cl. 600 (2012).

in this matter. The hearing went forward as scheduled, and the parties did not request the opportunity to file post-hearing briefs. The matter is ripe for adjudication.

IV. Applicable Legal Standards

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

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury” – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).²² In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause

²² Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. App’x 712 (Fed. Cir. 2004); *see also Spooner v. Sec’y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278.

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec’y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner’s ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).²³

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

²³ Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec’y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 Fed. App’x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then

required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and “complete” (i.e., presenting all relevant information on a patient’s health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec’y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner’s testimony and his contemporaneous medical records, the special master’s decision to rely on petitioner’s medical records was rational and consistent with applicable law”), *aff’d*, *Rickett v. Sec’y of Health & Human Servs.*, 468 F. App’x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec’y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec’y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff’d*, 993 F.2d at 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter’s symptoms.”).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec’y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den’d*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec’y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at *19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than

those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec’y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). See *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). “The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec’y of Health*

& Human Servs., 94 Fed. Cl. 53, 66-67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner’s case. Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec’y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den’d*, 108 Fed. Cl. 743 (2013), *aff’d*, 540 Fed. App’x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); *see also Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

D. Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, with Petitioner for her part filing approximately 65 separate items. But not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner’s case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec’y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) (“[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision”) (citation omitted); *see also Paterek v. Sec’y of Health & Human Servs.*, 527 F. App’x 875, 884 (Fed. Cir. 2013) (“[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered”).

ANALYSIS

I. *Althen* Prong One

The reliability of Petitioner's causation theory is immediately called into question in light of Respondent's effective cross examination regarding Dr. Nemechek's qualifications and expertise. Dr. Nemechek has a demonstrated interest in autonomic damage and the relationship between the autonomic nervous system and other illnesses, and appears to have attempted to develop that interest through personal study, but he has been persuasively shown by Respondent to lack a trustworthy grounding in such topics, whether in terms of his training or clinical expertise. His voicing of opinions in this case does not automatically entitle them to credence, as it is well understood in the Program that I am not obligated to accept an expert's opinion *ipse dixit*, but may weigh the expert's credentials and competence in evaluating it as part of the first *Althen* prong analysis. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also Madariaga v. Sec'y of Health & Human Servs.*, No. 02-1237V, 2015 WL 6160215, at *7 (Fed. Cl. Spec. Mstr. Sept. 26, 2015). Overall, the basis for Dr. Nemechek's expertise on autonomic matters was never established by Petitioner.

Nevertheless – Petitioner has *also* offered numerous pieces of medical and scientific literature to support the causation theory Dr. Nemechek advanced, and has also attempted to articulate that theory elsewhere, such as in her prehearing filing. *See* Petitioner' Pre-hearing Submission, dated Apr. 20, 2017 (ECF No. 39) (“Petitioner's Pre-hearing Submission”) at 10-12. Sufficient evidence has therefore been offered to review whether that theory stands on its own based on the “more likely than not” evidentiary test, even if the expert tasked with providing it was unpersuasive. *See Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009).

Petitioner maintains that her syncopal condition was caused by damage to the sympathetic branch of the autonomic nervous system, which was in turn the product of a neuroglycemia stimulated by the HPV vaccine doses she received over time. *See* Petitioner's Pre-hearing Submission at 14-15. She offered little in the way of direct evidence associating the vaccine, or any other, to her injury (although it is axiomatic in the Program that direct proof need not be offered to prevail),²⁴ but what she did offer is not particularly compelling. Kinoshita, for example, involved

²⁴ Although I am not bound by the decisions of other special masters, even to the extent they involve the same vaccine and injury, I note that those few written decisions involving the HPV vaccine and injuries comparable to what Ms. Combs alleges herein do not favor her theory. *See, e.g., L.A.M. v. Sec'y of Health & Human Servs.*, No. 11-852V, 2017 WL 527576 (Fed. Cl. Spec. Mstr. Jan. 31, 2017) (HPV vaccine not found to cause POTS); *Turkupolis v. Sec'y of Health & Human Servs.*, No. 10-351V, 2014 WL 2872215 (Fed. Cl. Spec. Mstr. May 30, 2014) (HPV vaccine not shown to cause neurocardiogenic syncope). By contrast, in one of the only decisions I have found involving HPV vaccine and syncope, an entitlement finding was premised on Respondent's concession that “the *immediate* temporal association between [the petitioner's] receipt of the Gardasil vaccine and her syncopal episode was medically

a very limited number of case studies (which in turn also involved disorders distinguishable from the present circumstances, such as POTS). *See R.V. v. Sec’y of Health & Human Servs.*, No. 11-504V, 2016 WL 3882519, at *41 (Fed. Cl. Spec. Mstr. Feb. 19, 2016) (“individual patient case reports . . . are not, in general, strong evidence of causation”) (internal quotation marks omitted), *mot. for rev. denied*, 127 Fed. Cl. 136 (2016). Kinoshita’s findings were also persuasively rebutted by Respondent’s expert as not subsequently corroborated. Tr. at 184, 205-06, 218.

Beyond the above, Petitioner could not substantiate her theory with even indirectly-relevant reliable scientific or medical evidence. Her centerpiece argument about microglial activation leading to chronic hypoglycemia was particularly unpersuasive. As Dr. Low noted, such arguments were especially thin and loose, and required the application of literature like Cunningham, which involved severe neurodegenerative diseases having no bearing on the present circumstances, while also assuming a chronic, pathologic impact of cytokines that has not been demonstrated to be possible after the HPV vaccine, or to be causal of repeated syncopal episodes. Such evidence simply did not establish a reliable, plausible theory for how any vaccine, let alone the HPV vaccine, might encourage chronic hypoglycemia sufficient to result in ongoing syncope.

II. *Althen* Prong Two

Even if I had found that Petitioner’s theory had sufficient evidentiary heft to support an *Althen* prong one determination in her favor, the medical record does not allow for the conclusion that the HPV vaccine more likely than not “did cause” Petitioner’s syncope. There is no record evidence that Ms. Combs was experiencing any kind of reaction to any of the doses of HPV vaccine she received, in the form of proof of ongoing inflammation or some test result that would permit an inference of an existing process (for example, proof of the chronic cytokine production that Dr. Nemechek opined was connected to Petitioner’s alleged microglial activation). Mrs. Howard’s claim that her daughter’s dizziness preceded her fall in March 2012 was unsupported by the medical record (which made no mention of dizziness as precipitating the fall) as well as the circumstances of the accident, which were consistent with the location of the occurrence. *See* Tr. at 49-53.

In addition, no treaters ever proposed that any HPV dose Petitioner received had anything to do with her condition. Tr. at 241. Other than the temporal association between Petitioner’s episodes and her vaccinations, nothing in the record would reasonably link one to the other. There is no discernible pattern of reaction from Petitioner’s first dose of the HPV vaccine to the last, nor evidence that reactions to subsequent doses were more powerful than earlier ones, thereby undermining the conclusion that Petitioner experienced a “re-challenge” reaction. And as Dr. Low pointed out, Petitioner’s argument that “symptoms” worsened after the second or third dose was

appropriate.” *Vanscoy v. Sec’y of Health & Human Servs.*, No. 13-266V, 2013 WL 3871008, at *1 (Fed. Cl. Spec. Mstr. July 3, 2013) (emphasis added).

less durable evidence of re-challenge than test results establishing a greater number of relevant biomarkers. Tr. at 224. Otherwise there was absolutely no proof offered that Petitioner's autonomic nervous system was damaged; Petitioner largely relied upon evidence of her syncopal spells to establish such damage.²⁵

In contrast to the inadequate quality of Dr. Nemechek's opinion, Dr. Low provided a thorough and persuasive interpretation of the medical record that strongly supports the conclusion that Petitioner's syncope was vasovagal in nature, as her treaters proposed. His counterintuitive argument that in fact Ms. Combs's presentation was *consistent* with a healthy autonomic system, rather than evidence of the contrary, was particularly compelling. Dr. Low's impressive background in the study of autonomic matters gave his opinion significant ballast. He not only was amply qualified to testify on the subjects of the autonomic system and what constitutes damage to it, but is in fact one of the foremost such authorities in the entire U.S. It was entirely reasonable to place considerable weight on the pronouncements of such an expert.

I am mindful that it is not the special master's function to propose what the proper diagnosis for an individual *is*. See *Andreu*, 569 F.3d at 1382 (quoting *Knudsen*, 35 F.3d at 549). However, I am called upon to determine what diagnosis the *evidence* best supports. In this case, that evidence far better supports the conclusion that Ms. Combs suffered from vasovagal syncope of an unknown etiology, as her treaters seem to have concluded, rather than due in any respect to autonomic damage caused by the HPV vaccine.

III. *Althen* Prong Three

Because Petitioner's causation theory was so unpersuasive and unreliable, I do not need to evaluate the reasonableness of her arguments about the timeframe in which her syncope began. See, e.g., *Lasnetski v. Sec'y of Health & Human Servs.*, 128 Fed. Cl. 242, 264 (2016), *aff'd*, 696 F. App'x 497 (Fed. Cir. 2017) (not error for special master to forego *Althen* analysis after determining that a petitioner had not in fact experienced the disease or illness alleged to have been vaccine-caused). I will observe, however, that in support of this *Althen* prong, Petitioner can point to little more than the fact that she experienced her "episodes" after the vaccine's administration – a temporal relationship which is widely understood in the Program to be insufficient evidence for a causation determination. See, e.g., *Morris v. Sec'y of Health & Human Servs.*, No. 13-601V, 2017 WL 2461226 (Fed. Cl. Spec. Mstr. May 9, 2017). Moreover, and as noted above, Ms. Combs took *longer* to experience another syncopal episode after the third dose of HPV vaccine than the second, undercutting the conclusion that her immune system was primed to react to it. Petitioner

²⁵ In other cases, I have noted the circular quality of arguments that proof of a symptom or reaction is evidence in support of Petitioner's causation theory at work. See, e.g., *Morris v. Sec'y of Health & Human Servs.*, No. 13-601V, 2017 WL 2461226, at *14-15 (Fed. Cl. Spec. Mstr. May 9, 2017). If a causation theory cannot be corroborated by some indirect evidence, it cannot be enough to point to the claimant's injury to substantiate the theory.

did not otherwise establish that the symptoms she experienced post-vaccination occurred in a medically appropriate timeframe.²⁶

CONCLUSION

The record does not support Petitioner's contention that the HPV vaccine caused her to develop syncope, and the expert support offered for her claim was deficient. Petitioner has therefore not established entitlement to a damages award, and I must DISMISS her claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.²⁷

IT IS SO ORDERED.

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

²⁶ For comparison purposes, there is some utility in considering what a Table-based syncope injury claim looks like in terms of onset. Every Table claim based on post-vaccination syncope requires establishing that the syncope began within an *hour* of receipt of the relevant vaccine. *See, e.g.*, §100.3(I)(D) and (II)(D). Even in those rare non-Table circumstances where a claimant has succeeded on such a claim, onset has been found to have begun soon after vaccination - not the month to two-month period at issue (arguably) in this case. *See, e.g., Vanscoy*, 2013 WL 3871008, at *1.

²⁷ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.