In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-278V
(Not to be published)

* *	Special Master Corcoran
MELANIE YALACKI, *	
Petitioner, *	Filed: January 31, 2019
v. *	Entitlement; Hepatitis B Vaccine; Chronic Fatigue Syndrome ("CFS"); Postural Orthostatic Tachycardia Syndrome ("POTS"); Autoimmunity; Medically-Acceptable Timeframe.
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
Respondent. *	
* *	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner.

Sarah C. Duncan, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On April 10, 2014, Melanie Yalacki filed a Petition under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]), alleging that the Hepatitis B ("Hep B") vaccine she received on June 2, 2011, caused her to suffer chronic fatigue syndrome ("CFS") and/or postural orthostatic tachycardia syndrome ("POTS"). Pet. at 1–2 (ECF No. 1).

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[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means 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 published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

A hearing in this matter was held on January 22–23, 2018. After consideration of the record and testimony provided at hearing, I find that Petitioner is not entitled to a compensation award. As discussed in more detail below, the Petitioner has not offered a reliable theory explaining how the Hep B vaccine could cause either of her alleged injuries. In addition, there are legitimate questions as to whether Petitioner actually suffered from CFS or POTS—but assuming that she did, the medical record does not support the conclusion that the vaccine likely caused either injury. The vaccination at issue was simply too remote in time from the record evidence most supportive of either diagnosis, while the symptoms she points to that occurred closer in time to vaccination either do not support her alleged injuries or can be explained by her pre-vaccination medical history.

I. Factual Background

Pre-Vaccination History

Mrs. Yalacki's medical history reflects numerous occasions on which she sought a physician's care. In the three years preceding the June 2011 vaccination in question, Petitioner sought treatment for a wide variety of injuries that ranged from minor to serious. These include (but are not limited to) muscle and joint pain, eye problems, dehydration, skin issues, and upper respiratory infection ("URI") symptoms.[3] *See generally* Ex. 1, filed Apr. 11, 2014 (ECF No. 5-1). Some of these doctor's visits were objectively reasonable—for example, Petitioner sought care for whiplash, a cervical sprain, and lumbar strain resulting from an April 30, 2010 car accident. *Id.* at 288. But overall, Mrs. Yalacki's medical records reveal that she regularly obtained medical assistance for general health concerns (some of which, in retrospect, do not appear to have merited immediate attention).

The pre-vaccination medical record also establishes that the Petitioner intermittently complained of symptoms very similar to those she allegedly experienced after receiving the Hep

[3] *See, e.g.*, Ex. 1 at 3–4 (ganglion cyst and wrist tendonitis due to hair twisting in May 2008); *id.* at 28 (bilateral hand and finger pain in July 2008); *id*. at 55–56, 64–65, 68 (deep joint and muscle pain in the upper extremities and a scratch on her eye from her fingernail in September 2008); *id*. at 80–82, 89–90 (bilateral hand and finger pain, tingling, and burning, back pain and inflamed eyelid glands in October 2008); *id*. at 94–96, 102 (bilateral arm pain, hair pulling, URI symptoms, and body aches in November 2008); *id*. at 104, 106–07, 110 (eye floaters, right eye "turning in," and feeling dehydrated after being in a sauna in December 2008); *id*. at 111–14 (severe body aches in January 2009); *id*. at 145–46 (weeks of bilateral foot tingling and toe and calf cramps during exercise in February 2009); *id*. at 189–92, 197–99 (acne and neck strain in June 2009); *id*. at 238–39 (ankle injury in November 2009); *id*. at 247–49 (left knee pain and metatarsalgia in February 2010); *id*. at 253, 270–73, 302–03 (acne; bilateral knee, foot, and ankle pain in March 2010); *id*. at 282–83 (shin contusion in April 2010); *id*. at 288–92, 306–09, 321–23, 329–31, 420–21, 430–31 (car accident-related lower back and neck pain in May, June, and December 2010); *id.* at 316–17, 337–40, 343–45 (corneal dystrophy, dry eye syndrome, and groin pain after bike riding in June 2010); *id*. at 353–54, 359–60 (finger injury and back pain in July 2010); *id*. at 404–05 (lower back pain in November 2010); *id*. at 454–58, 475–76 (allergic reaction to bed covers, jaw pain, and lower back pain in February 2011); *id*. at 496–97, 500–01 (stomach ache and lower back pain in March 2011); *id*. at 504–10, 523–34 (cough, shortness of breath, and lower back pain in April 2011); *id*. at 529–30, 539–40 (lower back pain and request for valium refill in May 2011).

B vaccine. For example, on June 24, 2008 (three years prior to the vaccination in question), Mrs. Yalacki sought treatment for dizziness, nausea, shakiness, and near syncope after consuming several doughnuts. Ex. 1 at 9–13. A few months later, on October 2, 2008, Petitioner complained of fatigue, dizziness, nausea, and increased heart rate after taking Vicodin. *Id*. at 70. On four occasions in January 2009, she reported fatigue, diffuse muscle aches, "burning in [her] chest," leg pain, and concern that she had lupus attributable to chemicals in her new car. *Id*. at 119–20, 126–27, 129–33. And two years later, on February 25, 2011, after being diagnosed with mild anemia, Petitioner reported that she was "freaking out" and that she had "felt like passing out a couple of times." *Id*. at 482–83.[4]

Receipt of Hepatitis B Vaccine and Purported Immediate Reaction

On June 2, 2011, Mrs. Yalacki (then thirty-three years old) saw Laura Jarrell, M.D., at the Kaiser Permanente[5] facility in Lakewood, Colorado, to discuss treatment for chronic back pain. Ex. 2 at 5–7, filed Apr. 11, 2014 (ECF No. 5-2). On the same date, Petitioner received her third Hep B vaccine (the first two having been administered without incident on May 9, 2000, and November 7, 2000). *Id.* at 6, 18, 39; Ex. 1 at 444.[6]

Almost immediately after, Mrs. Yalacki began reporting to treaters that she was experiencing an adverse reaction. She phoned the Kaiser Permanente nurse advice line on the afternoon of June 2, 2011, requesting a call back regarding body aches and fatigue. Ex. 2 at 16. The nurse returned her call at 5:35 p.m., at which time Mrs. Yalacki stated that she was very tired and had muscle aches, attributing her symptoms to the Hep B vaccine she had received earlier that day. *Id*. Less than one hour later she called the advice line a second time, repeating her concern that she "fe[lt] bad" after having received the Hep B vaccine. *Id.* at 17. She called a third time the next morning, again expressing worries about a "vaccine reaction," that she pinpointed as having

[4] Besides seeking care for physical problems, the record reveals that in the years prior to vaccination, Petitioner also discussed concerns regarding her mental health with treating physicians. *See, e.g.*, Ex. 1 at 207–09 (July 15, 2009 report of depression and concern regarding short term memory loss and disorganized thoughts, which had begun years before); *id.* at 367–69 (July 29, 2010 report of severe depression after stopping breastfeeding); *id.* at 380–81 (September 24, 2010 report of problems coping with anxiety and depression for many years, but declining antidepressants or a mental health practitioner referral). However, Petitioner maintains that any such problems were under control immediately prior to her receipt of the Hep B vaccine, and that she was in fact doing well mentally at that time. Pet'r's Post-Hr'g Br. at 2, filed Aug. 20, 2018 (ECF No. 96); Tr. at 237, 241, 392–93; *see also* Ex. 1 at 295 ("depression stable"), 360 ("depression stable"), 405 (anxiety stable with one dose of valium per week).

[5] It appears from the medical record (which shows that Petitioner saw numerous different practitioners with the same practice focus—for example, family medicine or cardiology) that Mrs. Yalacki did not regularly see a single primary care physician. This may have been because her insurance was in the form of a health maintenance organization that allowed her to see any professional available at the time.

[6] It is unclear why eleven years elapsed between Petitioner's second and third Hep B vaccinations. The Centers for Disease Control and Prevention recommend a one-month gap between the first and second doses of Hep B, and a two-month gap between the second and third. *Immunization Schedules*, Centers for Disease Control and Prevention (Mar. 5, 2018), https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html.

begun within an hour and a half of the vaccine's administration, and leaving her bed-ridden and dizzy. *Id.* at 18. Based on such reports, the call log set forth an assessment of "reaction to immunization." *Id.*

Later in the day on June 3, 2011, Mrs. Yalacki returned to Dr. Jarrell based upon the alleged reaction she had experienced the day before. Ex. 2 at 22–24. Her exam, however, was normal, with no evidence of muscle weakness. *Id*. at 23. Dr. Jarrell's diagnosis was fatigue as a possible side effect of the vaccination, "though not compatible with allergic reaction," adding that an unrelated viral illness or Petitioner's pre-vaccination anemia might be contributory factors to the symptoms Petitioner reported. *Id*.

Despite Dr. Jarrell's initial assessment, Petitioner continued to express concerns about an ongoing reaction. Days after her appointment with Dr. Jarrell, Mrs. Yalacki called the nurse advice line on June 6, 2011, with similar complaints about muscle weakness and fatigue that she reported had lingered without improvement. Ex. 2 at 34. She reiterated her view that the Hep B vaccine was the source of her symptoms. *Id.* That evening, a different physician, Li-Fen Lee, M.D., evaluated Petitioner. *Id.* at 38. Noting that she was unable to keep her eyes open during the exam due to fatigue, Dr. Lee ordered bloodwork. *Id.*

Based on Mrs. Yalacki's demonstrated fatigue and her indications that she did not feel she could adequately care for herself under the circumstances, Dr. Lee proposed that she go to Exempla St. Joseph's emergency room ("ER"). Ex. 2 at 39. There, Petitioner again reported five days of marked fatigue since receiving the Hep B vaccine. Ex. 5 at 4, filed Apr. 11, 2014 (ECF No. 5-5). Her exam was normal, however, and ER treaters did not propose that the vaccine was causal (or, for that matter that any other "typical reaction to vaccine" was present). *Id.* at 5. Petitioner was discharged that same evening with a diagnosis of fatigue. *Id.* at 5–7.

In the following days, Mrs. Yalacki continued to express alarm about her purported vaccine reaction. Specifically, on June 7 and June 15, 2011, Petitioner again reported complaints to Dr. Jarrell similar to what she had previously reported. *See* Ex. 2 at 47, 56–57. In response, Dr. Jarrell contacted an infectious disease specialist, and reported to Petitioner that this specialist had preliminarily stated that although mild fatigue could occur in association with vaccination, Petitioner's claimed symptoms were not consistent with what was ordinarily reported. *Id.* at 51. Dr. Jarrell proposed additional bloodwork to check for evidence of an infection or inflammatory disease. *Id*.

At her visit with Dr. Jarrell on June 15, 2011, Petitioner brought in "multiple web sites and blog sites" for Dr. Jarrell to review about "stories of people who claim to be sick themselves or know someone who has either been sick or died after receiving the hep B shot." Ex. 2 at 56. Dr. Jarrell, however, again expressed doubt that Petitioner's symptoms had anything to do with the

vaccination, noting that Petitioner had received it before without incident, and that her blood tests had raised no notable concerns. *Id.* at 57. She nevertheless referred Petitioner to an infectious disease specialist for further evaluation. *Id.* at 57, 69. Prior to that visit, Petitioner saw Heather Burton, M.D., on June 16, 2011. After recounting symptoms and a history much as before, Dr. Burton proposed depression or anxiety as an explanation for Mrs. Yalacki's condition, although Petitioner declined to pursue mental health treatment. *Id.* at 87.

At. Dr. Jarrell's referral, Mrs. Yalacki saw infectious disease specialist Miguel Mogyoros, M.D., on June 20, 2011. Ex. 2 at 67–69. She recounted the same post-vaccination history and symptoms as before, with Dr. Mogyoros noting that Petitioner had been "looking up vaccine side effects in the internet and is convince[d] her symptoms are due to this vaccine." *Id.* at 67. Consistent with prior treaters, Dr. Mogyoros expressed the view that the Hep B vaccine was not likely the source of Petitioner's symptoms, and noted as well that bloodwork revealed no identifiable other problems, but that Mrs. Yalacki was "not very interested" in his opinion and seemed convinced the vaccine was causal of her alleged symptoms. *Id.* at 68. Any blood testing Dr. Mogyoros performed was also negative. *Id.* at 72. He did, however, agree to report the claimed reaction to the Vaccine Adverse Event Reporting System ("VAERS"). *Id.* at 68.

Although numerous treaters informed Petitioner in the same month she received the Hep B vaccine that (a) they could not identify the source of her symptoms, and (b) they did not deem it likely that the vaccine was causal of those symptoms, Mrs. Yalacki continued to seek treatment,[7] including self-admission to two different hospital ERs where she informed providers of her suspicions that the vaccine was related to her illness. *See, e.g.*, Ex. 6 at 3–4, filed Apr. 11, 2014 (ECF No. 6-1) (June 16, 2011 visit at Porter Adventist Hospital ER; neurology work-up recommended); Ex. 5 at 14–20 (June 18, 2011 visit to Exempla St. Joseph ER). Again, no etiology was proposed for Petitioner's symptoms, nor did treaters identify the Hep B vaccine as causal (despite Petitioner's assertions to the contrary).

After the second of these ER visits, Mrs. Yalacki received a more in-depth neurologic work-up from Lynsee Lang, M.D., on June 22, 2011. Ex. 2 at 104–08. Around this time, Petitioner also began to report experiencing multiple convulsion spells per day. *Id.* at 106. Dr. Lang noted, however, that prior neurologic evaluations performed at ERs had discounted seizure as an explanation for Petitioner's condition, and an MRI produced normal results. *Id.* The exam was

[7] Treaters also continued to propose to Mrs. Yalacki that her symptoms likely had a psychological component—an assessment that she rejected. Thus, on June 30, 2011, Petitioner returned to Dr. Jarrell and admitted that she was depressed, but did not want to be treated for fear of being "pigeon-holed," and disputed the conclusion that she was "unstable," maintaining her belief (based on her own independent research) that the Hep B vaccine explained her symptoms. Ex. 2 at 123–24. Dr. Jarrell nevertheless "strongly recommended" that Petitioner treat her depression (based upon the opinion that doing so would ameliorate her symptoms), but Petitioner refused. *Id.* at 124. The following month, another neurologic consult produced the opinion that Petitioner's spells were pseudoseizures (which are deemed psychological in origin rather than evidence of neurologic injury). *Id.* at 155–56; *Dorland's Illustrated Medical Dictionary* 1546 (32nd ed. 2012) (hereinafter "Dorland's").

otherwise unremarkable, as was an electroencephalogram Dr. Lang subsequently ordered. *Id.* at 107, 117. Dr. Lang concluded that Petitioner's spells were unlikely true seizure activity "and could be entirely unrelated to vaccination other than [as] a possible stressor that could have exposed this phenomenon." *Id*. at 108. Despite this work-up, Petitioner that same day requested additional factors about her purported symptoms be added to the existing VAERS report, to "make sure other people don't get sick from this vaccine." *Id.* at 79.

Defining Alleged Reaction as CFS or POTS

As Petitioner continued to seek medical guidance in the summer of 2011 for her alleged vaccine-caused symptoms, she also began proposing her own characterizations of those symptoms or exploring alternative explanations.

Thus, on July 8, 2011, Julie Cohen, M.D., consulted on Petitioner's case. Ex. 2 at 136–37. As before, Petitioner recounted a litany of post-vaccination symptoms, including several she had not previously reported: cognitive delay, difficulty remembering basic words, and fainting. *Id*. at 136. Dr. Cohen proposed some repeated testing or seeking second opinions (for example, with respect to the neurologic consult that Petitioner had received the month before but disputed). *Id.* at 142. A few days later, however, on July 11, 2011, Mrs. Yalacki called Dr. Cohen's office and stated that she believed she was suffering from CFS. *Id*. at 146. The next day, she repeated this assertion (although the record of her subsequent call uses the formal medical term "myalgic encephalomyelitis" in lieu of CFS). *Id.* at 150.

On July 28, 2011, Dr. Cohen evaluated Petitioner for syncopal episodes that she reported had occurred every other day for a week. Ex. 2 at 192. Dr. Cohen's examination of Mrs. Yalacki was unremarkable, however, and she concluded that Petitioner did not have CFS, recommending instead that Petitioner obtain a Holter monitor evaluation[8] and echocardiogram to determine an explanation for her syncopal episodes. *Id*. at 192–93. Subsequent testing over the next month for Petitioner's convulsion-like spells confirmed that they did not meet the clinical criteria for seizures. Ex. 8 at 25–26, filed Apr. 11, 2014 (ECF No. 6-3). Mrs. Yalacki nevertheless "continued to hold on to the idea that these [spells] occurred as a result of the HBV vaccination (which we feel is not the case)." *Id*. at 23.

On September 8, 2011, Mrs. Yalacki saw cardiologist Joseph Abruzzo, M.D. Ex. 2 at 283–84. Again she repeated her history since receiving the Hep B vaccine. *Id.* at 283. The Holter monitor test revealed sinus rhythm with heart rate ranges between 50 and 140 beats per minute ("BPM"), and the echocardiogram was normal. *Id.* Dr. Abruzzo's initial evaluation, after review of her file and the substantial testing she has already undergone (none of which had been positive

[8] Holter monitors are attached to the body and measure a subject's heart rate over twenty-four-hour periods. Tr. at 37.

for any understood etiology), was that Petitioner possibly was experiencing a "[s]yndrome of autonomic neuropathy" that was at least temporally associated with the Hep B vaccine administration. *Id.* at 284.[9] To test this impression, Dr. Abruzzo proposed that Mrs. Yalacki treat what could be an orthostatic condition with "aggressive water and salt intake," and also scheduled her for a tilt table test (in which an individual's orthostatic readings are continuously taken while the subject is secured to a flat table that is then tilted up)[10]—the test deemed most reliable for diagnosing POTS (*see* Eduardo E. Bennaroch, *Postural Tachycardia Syndrome: A Heterogeneous and Multifactorial Disorder*, 87 Mayo Clinic Proc. 1214, 1220 (2012), filed as Ex. H Tab 1, June 30, 2016 (ECF No. 42-8))—for later that month. *Id.* The tilt table test was performed on September 20, 2011, as scheduled, and although it was terminated after thirteen minutes due to leg pain, Dr. Abruzzo (observing that "the HR [heart rate] and BP [blood pressure] did not vary in an important way from baseline") concluded that it revealed no evidence of autonomic dysfunction. Ex. 5 at 84.[11] Petitioner's heart rate increased by only ten BPM over the exam period. *Id.*

Treater Support for Petitioner's CFS/POTS Diagnoses

Despite the aforementioned records (which are largely unsupportive of the conclusion that Petitioner suffered from either CFS or POTS), Petitioner did later receive treater evaluations supportive of some of these diagnoses—although it is not clear from the record how comprehensive or reliable these diagnoses are.

On September 27, 2011, Petitioner presented to a new primary care physician ("PCP"), Anisa Moore, M.D. Ex. 2 at 335–36. Dr. Moore's examination of Mrs. Yalacki produced only normal results, but based on the history she reported (and without any indication that Dr. Moore had reviewed the expansive prior medical record), Dr. Moore diagnosed her with CFS. *Id.* at 335. In so doing, Dr. Moore noted her view that, except for the temporal requirement, Mrs. Yalacki met

[9] The record from this same time period memorializes a call Mrs. Yalacki made to the nurse line in which she represented that Dr. Abruzzi had definitively informed her that her symptoms were attributable to the Hep B vaccine, and asked that this be documented in her record. Ex. 2 at 291. The nurse taking the call reviewed the same record referenced above, and on that basis responded that in fact all Dr. Abruzzo had stated was that there was a *temporal relationship* with the vaccine. *Id.*

[10] The standard tilt table test entails the patient remaining in a supine position for twenty minutes, followed by ten minutes tilted upright, and that the heart rate and blood pressure should be measured minute by minute. Tr. at 265–66. Preparation for the test begins the day before, to ensure that the patient has consumed sufficient fluids and has not consumed alcohol or medications that might interfere with the results. *Id.* at 265.

[11] Also in September of 2011, a rheumatologic work-up of Petitioner (intended to evaluate arthralgias that had been allegedly present since the Hep B vaccination) found no evidence of any joint inflammation or damage, and no signs to suggest inflammatory arthritis, connective tissue disorder or evidence of serum sickness-like disorder. Ex. 2 at 312–13.

the Center for Disease Control's ("CDC") criteria for CFS.[12] *Id.* Dr. Moore did not express an opinion as to the causal role of the Hep B vaccine, although she forthrightly did not rule out the possibility. *Id.*[13] Dr. Moore subsequently urged Mrs. Yalacki to obtain treatment for CFS from a specialist, but it is not evident from the record that Petitioner ever acted on this recommendation. *Id.* at 359.

Another primary care physician Petitioner consulted in October 2011—Leslie Pearson, M.D.—also concurred that Petitioner's self-reported symptoms described CFS, although Dr. Pearson added that a "MH [mental health] disorder" was likely contributing to Petitioner's symptoms. Ex. 2 at 402–03. Like Dr. Moore, moreover, Dr. Pearson stressed the importance of obtaining proper specialized treatment for CFS (including cognitive therapy and graduated exercise), and Dr. Pearson refused to sign short term disability paperwork for Petitioner without Petitioner's agreement to actively pursue such treatment. *Id.* at 402.

In January 2012, Petitioner saw yet another PCP, Andrea Fedele, M.D. (who, as discussed below, also testified at hearing). Ex. 2 at 425–28. Based on Petitioner's subjective symptoms and a review of the CDC criteria, Dr. Fedele confirmed the CFS diagnosis, adding that "it is most consistent by history as due to the vaccination received on 6/2/2011." *Id*. at 428. As with Dr. Moore's diagnostic assessment, however, it does not appear from the January record of the visit to Dr. Fedele that she reviewed or took into account Petitioner's detailed prior history (although she did purport to have reviewed prior testing results). *See id.* at 428.

Petitioner's condition improved substantially beginning in early March of 2012, with fewer body aches and less fatigue, as Dr. Fedele recognized. *See* Ex. 2 at 457–58. By June of that year,

[12] The CDC states that a CFS diagnosis requires the following: 1) "clinically evaluated, unexplained persistent or relapsing chronic fatigue that is of new or definite onset (i.e., not lifelong), is not the result of ongoing exertion, is not substantially alleviated by rest, and results in substantial reducation [*sic*] in previous levels of occupational, educational, social, or personal activities;" and 2) "concurrent occurrence of four or more of the following symptoms: substantial impairment in short-term memory or concentration; sore throat; tender lymph nodes; muscle pain; multi-joint pain without swelling or redness; headaches of a new type, pattern, or severity; unrefreshing sleep; and post-exertional malaise lasting more than 24 hours," all of which must persist or recur over six consecutive months and may not have predated the fatigue. Ex. 125 at 1, filed Nov. 21, 2017 (ECF No. 75-2). The CDC also includes a list of conditions that *exclude* a diagnosis of CFS, including major depressive disorders with psychotic or melancholic features, among others. *Id.*

[13] Later on, however, Petitioner took a more pointed approach in challenging Dr. Moore's reluctance to link the Hep B vaccine to her symptoms. On October 7, 2011, Mrs. Yalacki and her husband returned to Dr. Moore. Ex. 2 at 358–59. The record from this visit reveals Dr. Moore's recollection that Petitioner was "very invested in having the treating physician and Kaiser Permanente as a corporation acknowledge that the hepatitis B vaccine caused p[atien]t's symptoms and condition," but when Dr. Moore attempted to emphasize that she considered it more important to provide good treatment to Petitioner than to identify the etiology of a condition that could not be "undone" (as the vaccine's damage, if any, occurred when it was administered the prior June), Petitioner and her husband became very angry and accusatory, insisting that their own research revealed an association, and questioning Dr. Moore's competence to opine on the possibility of vaccine causation. *Id.* at 359.

Petitioner was able to do basic tasks such as getting groceries, and while she experienced some fatigue, she noted that resting helped her feel better. *Id.* at 465. And then at a September 19th visit, Petitioner reported that she was doing "much better" and was "far more functional." *Id.* at 472. She was able to resume teaching first grade that fall. *Id.*

Mere days after that September 19, 2012 visit, however, Petitioner's health took a dramatic turn for the worse. *See* Ex. 2 at 478. She called Kaiser Permanente on September 24th, complaining of a headache, body aches, and fatigue. *Id.* Dr. Fedele followed up via telephone the following day, at which time Mrs. Yalacki reported that she had experienced a "crash" four or five days prior. *Id.* at 480. She again called the Kaiser Permanente line on September 28th, stating that she had experienced exhaustion, body aches, headaches, and pain under her arms since receiving the Hep B vaccine in June 2011. *Id.* at 484. However, Dr. Fedele did not perceive Petitioner's condition to be as bad as it had been the previous year upon returning her call later that afternoon. *Id.* at 485.

Subsequent visits to various physicians did not confirm the CFS diagnosis provided by previous treaters. For example, in November 2012 Mrs. Yalacki saw another neurologist, Julie Seibert, M.D. (a referral from Dr. Fedele) complaining of heart palpitations. Ex. 2 at 537–39. Dr. Seibert did not believe that Petitioner had any neurologic problems, however, nor did she see evidence of autonomic dysreflexia, although she proposed that Petitioner consult with a cardiologist on the latter point. *Id.* at 538. Mrs. Yalacki saw Dr. Abruzzo again, in February 2013, at which time he reviewed a newer echocardiogram and Holter monitor results, noting that both were normal. *Id.* at 625. He reaffirmed that Petitioner's September 2011 tilt table test had been negative for any possible autonomic dysfunction. *Id.*

Petitioner nevertheless continued to seek referrals for new neurologists and cardiologists (based in part on her own POTS and autonomic dysreflexia research) to obtain second and third opinions. Ex. 2 at 630. To that end, on February 26, 2013, Mrs. Yalacki saw neurologist Karen Rollins, M.D., who, noting Mrs. Yalacki's normal neurologic testing results, felt she did not have anything to add. *Id.* at 635–40. Dr. Rollins did, however, opine that (a) Petitioner did not have POTS, (b) her symptoms were unrelated to her June 2011 vaccination, and (c) further medical treatment was unnecessary. *Id.* at 636. Significantly (and in contrast to some treater records that were more deferential to Petitioner's claims, without independently verifying assertions made about her history), Dr. Rollins's treatment record includes a more expansive walkthrough of Petitioner's medical history post-vaccination, including her ER visits. *Id.* at 637–40.

The following month, on March 5, 2013, Mrs. Yalacki saw another cardiologist, Adam Betkowski, M.D. Ex. 2 at 665–68. He took note of Petitioner's negative tilt table test results, but performed his own in-clinic check of blood pressure and heart rate, measuring both while sitting and while standing. *Id.* at 667. He determined that her blood pressure and heart rate changes going from one posture to the other were enough to "suggest possibly [POTS] with possibly borderline

orthostatic hypertension." *Id.* Dr. Betkowski noted her heart rate as around 70 BPM during a seated physical exam, which increased to 120 to 130 BPM when she stood up. *Id.* Dr. Betkowski concluded that Petitioner "likely" had POTS, but recommended additional testing (including another tilt table test) in order to confirm the supposition. *Id.* at 668. Later that same month, Petitioner's plasma norepinephrine levels were tested, but found to be well within the normal range. Ex. 3 at 7, filed Apr. 11, 2014 (ECF No. 5-3).[14]

It does not appear from the record that a second tilt table test was ever performed despite Dr. Betkowski's recommendation. However, one year later (after Petitioner had moved to California from Colorado), in March 2014 Mrs. Yalacki saw a new PCP, Rebecca Smith, M.D. Ex. 12 at 1–3, filed June 18, 2014 (ECF No. 9-2). At her initial visit with Dr. Smith, Petitioner reported that she had in fact been diagnosed with POTS based on a tilt table test, that she had CFS, and that she had become "very ill" on June 2, 2011 after receiving a Hep B vaccine. *Id.*

One month later, Petitioner saw cardiovascular physician Brett Berman, M.D. Ex. 13 at 1–3, filed June 27, 2014 (ECF No. 10-1). She reported that she had been diagnosed with POTS in March 2013 (presumably relying on Dr. Betkowski's assessment based solely on standing/sitting measurements of heart rate and blood pressure). *Id.* at 1. She also informed him of the prior tilt table test performed in 2011, although Dr. Berman deemed the results "unclear" based on Petitioner's recollections. *Id.* Dr. Berman's examination revealed a regular heart rhythm with mitral regurgitation, and an echocardiogram performed at this time revealed "sinus rhythm at 93 with increased voltage and possible left ventricular hypertrophy with T-wave changes possibly secondary to repolarization abnormalities." *Id.* Dr. Berman's assessment was orthostatic hypotension, unspecified chest pain, mitral valve insufficiency/aortic valve stenosis, and nonspecific abnormal echocardiogram. *Id.*

In the spring of 2014, Petitioner visited Robert Gillespie, M.D., on two occasions. Ex. 12 at 5–7, 33–35. At her first visit with him on April 18th, she informed him that she had previously been diagnosed with POTS. *Id.* at 5. Dr. Gillespie performed a sit-stand test, upon which Mrs. Yalacki's heart rate increased by twenty-eight BPM while her blood pressure remained unchanged. *Id.* at 7. Based on her self-reported history and the sit-stand test results, Dr. Gillespie opined that she had POTS. *Id.* Noting that she attributed her condition to receipt of the Hep B vaccine, he remarked that he was unfamiliar with the idea that the vaccine could be causal. *Id.* At her second visit with Dr. Gillespie on May 22, 2014, Petitioner's heart rate increased from seventy-one to eighty-eight BPM in a sit-stand test, with her blood pressure again remaining unchanged. Ex. 12 at 34. Dr. Gillespie reiterated his view that she had POTS at this time. *Id.*

[14] It does not appear from the medical records filed in this case that Petitioner's plasma norepinephrine levels were tested at any time post-vaccination before March 24, 2013. As explained by Dr. Low at hearing, such results would have been helpful in showing whether Petitioner had POTS earlier in time. *See* Tr. at 277–78.

At Dr. Gillespie's referral, Petitioner went to yet another cardiologist, Elizabeth Noll, M.D., on July 2, 2014. Ex. 15 at 1–4, filed Aug. 6, 2014 (ECF No. 12-2). After performing an initial review of the records and an examination, Dr. Noll noted that "[a]lthough the diagnosis of POTS has been questioned, the patient has also demonstrated significant increase in heart rate during office exams when placed in an upright position." *Id.* at 1. Dr. Noll's assessment accepted the prior POTS diagnosis ("currently carries a diagnosis of [POTS]"), but she acknowledged that other testing (the Holter monitor, for example) did not support the diagnosis, and that the 2011 inconclusive tilt table test "reportedly did not demonstrate the typical heart rate increase seen within the initial phase of upright tilt," leading her to suggest that the test should be repeated. *Id.* at 3.

No further records of Petitioner's treatment since July 2014 have been filed. It also does not appear that Petitioner ever underwent a second tilt table test.

II. Fact and Expert Witnesses

A. *Petitioner's Witnesses*

1. Mrs. Melanie Yalacki

Petitioner testified both as part of her direct case and again in rebuttal. She maintained (somewhat contrary to the record as discussed above, at least with regard to the years immediately prior to vaccination) that before receipt of the third Hep B shot she was "very energetic" and had a "zest for life." Tr. at 236. She noted in particular that she had always been motivated in her work as a teacher. *Id.* at 237–39. She also testified about her passions for exercise and spending time with family. *Id.* at 240. She also recalled the enthusiasm and energy she had when planning a party for her mother prior to vaccination. *Id.* at 241.

After the June 2011 vaccination, however, Petitioner began to feel weak and "really tired" in a manner that she said was unusual. Tr. at 240. Her purported change in energy and overall health status prevented her from pursuing her career. In particular, she recalled that by the summer of 2012 (one year after the vaccination in question) she "started to feel a little better," and was able to obtain accommodations from her school administration to allow her to go back to work. *Id.* at 242. However, her health problems made it too hard to do so. *Id.* at 243.

In her rebuttal testimony, Mrs. Yalacki attempted to distinguish her pre-vaccination health status from thereafter. Thus, she recalled that immediately before the June 2011 vaccination, she was in the process of ending the school year (which, as a teacher, meant closing down her classroom), preparing for and hosting her son's seventh birthday party, and organizing the

aforementioned party for her mother. Tr. at 391–93. She exercised on the morning she received the Hep B vaccination, and overall she characterized her health at that time as "stellar." *Id.* at 394.

2. Dr. Andrea Fedele

Dr. Fedele was the first of two treating physicians to offer testimony on Petitioner's behalf. She also provided a one-page opinion letter. *See* Ex. 17, filed Apr. 7, 2015 (ECF No. 22-1). She testified about the circumstances of her treatment of Mrs. Yalacki in 2012–13, and specifically the bases for the CFS diagnosis she made.

Dr. Fedele practices family medicine in Colorado for Kaiser Permanente (in particular, the KP Foundation Health Plan), the health provider from whom Petitioner received much of the treatment at issue in this case. Tr. at 61–62, 104.[15] She provided medical services to Mrs. Yalacki between January 2012 and April 2013. *Id.* at 63.

Although Dr. Fedele has seen patients with CFS in her time as a physician, treatment of the condition is not a regular feature of her medical practice, and she admittedly lacks specialized expertise with it. Tr. at 104. She also has no specialized training in immunology, and Mrs. Yalacki was not her patient at the time of the 2011 vaccination at issue. *Id.* at 105–06.

At hearing, Dr. Fedele was questioned about her treatment of Mrs. Yalacki. Tr. at 63–83. She confirmed that she had diagnosed Petitioner with CFS slightly more than six months after Mrs. Yalacki received the Hep B vaccine. *Id.* at 63. Overall, she emphasized that her personal examination of Mrs. Yalacki revealed (or confirmed, based on Petitioner's self-reporting) fatigue, post-exertional malaise, unrefreshing sleep, cognitive impairment, and orthostatic symptoms—all of which are clinical indicia of CFS. *Id.* at 64, 81–84.[16] She obtained those indicia, however, from computer diagnostic information maintained by Kaiser Permanente, as opposed to her own individual expertise in treating others with CFS. *Id.* at 65, 105. She also noted that, although at certain points in 2012 Mrs. Yalacki appeared to be recovering from her CFS symptoms, these

[15] Dr. Fedele's curriculum vitae was not filed in this case.

[16] On cross examination, Respondent took issue with the record evidence purported to support certain of Dr. Fedele's findings with respect to CFS. Thus, Dr. Fedele allowed that shortness of breath was not equivalent to post-exertional fatigue (something Petitioner reported experiencing). Tr. at 93. She was also asked several questions about the strength of evidence supporting the conclusion that Petitioner was experiencing "unrefreshing sleep," acknowledging that although Petitioner reported being bed-ridden, this was more consistent with generalized fatigue. *Id.* at 97. In another instance, Dr. Fedele seemed to interpret being bed-ridden as proof of unrefreshing sleep. *Id.* at 74 (discussing October 22, 2012 record). Ultimately, however, because CFS can be diagnosed based on multiple criteria, I do not find that the evidentiary strength of the CFS diagnosis turns on whether in fact Petitioner actually experienced "unrefreshing sleep."

symptoms soon returned in a way that Dr. Fedele found to be consistent with CFS. *Id.* at 71–72 (discussing records pertaining to successive visits to Dr. Fedele in September 2012).

Dr. Fedele's testimony featured a review of all medical records documenting her treatment of Petitioner throughout the relevant time period. *See generally* Tr. at 63–83. She frequently read her notations in particular records aloud without additional comment. *See, e.g.*, *id*. at 68, 72, 73, 75–79. However, in some instances she provided context for her notes. For example, Dr. Fedele recalled that as of her first visit with Petitioner (on January 10, 2012), she did not have the benefit of a complete set of Petitioner's prior medical records. *Id.* at 103, 106; *see also* Ex. 2 at 425. Although Dr. Fedele stressed that her own examinations of Petitioner revealed symptoms of CFS, she admitted that records establishing similar symptoms before vaccination would have been relevant to the accuracy of her diagnosis. Tr. at 96. Her diagnosis was also in some respects based on Petitioner's self-reported symptoms; she accepted Petitioner's reported pain rather than verifying its sources in her examination. *Id.* at 94.

Dr. Fedele also addressed the issue of Petitioner's mental condition, which she conceded could have explained some of her symptoms such as fatigue. Tr. at 99–100. She acknowledged that she had not confirmed whether an underlying psychological problem could have contributed to Mrs. Yalacki's symptoms, noting that she relied on Petitioner's denial that she was experiencing depression or any related condition at the time Dr. Fedele was treating her. *Id.* at 99. She was, however, aware of Mrs. Yalacki's prior treatment for depression and other mental health problems, and allowed that evidence suggesting prior treaters had associated such underlying health mental issues with Petitioner's symptoms was relevant to the CFS diagnosis. *Id.* at 101–02.

In addition to her testimony (and despite her admitted lack of immunologic expertise), Dr. Fedele also offered a written letter supporting vaccine causation. *See* Ex. 17. At trial, however, she admitted that, although her letter assumed vaccine causation based on the onset of Petitioner's symptoms shortly after receiving the Hep B vaccine, she could not establish causality from a medical or scientific standpoint. Tr. at 83, 92–93, 106–07. In addition, although Dr. Fedele noted that symptoms experienced by Petitioner before vaccination might be distinguishable from those she experienced came after, she agreed that the Hep B vaccine could not logically be deemed causal of any pre-vaccination symptoms. *Id.* at 108, 109.

3. Dr. Robert Gillespie

Dr. Gillespie was one of the treating cardiologists Petitioner saw in 2014, after she moved to California. He did not provide a written report, but testified at hearing in support of the contention that Petitioner was accurately diagnosed with POTS. Tr. at 167–68.

Dr. Gillespie received his B.S. from the University of California-Los Angeles ("UCLA") and his M.D. from the University of Chicago, then completed a residency at Loyola University Medical Center in Maywood, Illinois, followed by a fellowship in cardiovascular medicine at

UCLA. Ex. 132 at 1–2, filed Dec. 22, 2017 (ECF No. 80-1). He specializes in cardiovascular disease, and his practice is based in San Diego, California. Tr. at 165–66. He acknowledged that he lacks specialized expertise in POTS, although he has diagnosed it and felt that his overall experience with heart issues made him competent to render an opinion in this case as to its applicability to Petitioner. *Id.* at 179.

Dr. Gillespie only saw Mrs. Yalacki on two occasions, both in 2014, and he recalled having her as a patient. Tr. at 167, 170–71. During the first visit in April 2014, Petitioner informed Dr. Gillespie that she had previously been diagnosed with POTS. *Id.* at 169. As he did not possess all of her prior medical records at the time of this initial visit, Dr. Gillespie attempted to confirm the diagnosis, and therefore sought to perform a sit-stand test to measure orthostatic hypotension (a drop in blood pressure) and any heart rate increase when Petitioner stood up (in comparison to readings obtained while she was seated). Tr. at 169–70; Ex. 12 at 6–7. The orthostatic readings revealed no substantive change in blood pressure, but Petitioner did display a heart rate increase of twenty-eight BPM and became symptomatic—that is, she felt so faint upon standing that she had to lie down. Tr. at 170, 179–80. In Dr. Gillespie's view, these results were consistent with a POTS diagnosis, although he allowed that the heart rate increase was just under the thirty BPM requirement for the diagnosis, and that his records from that visit did not corroborate his recollection of Petitioner being symptomatic after standing. *Id.* at 179–80.

Dr. Gillespie next saw Petitioner in May 2014. Tr. at 171. She provided him with her past medical records at this visit, which he reviewed briefly in in conjunction with his examination of her. *Id.* At this visit, Petitioner showed a heart rate increase on standing of only eighteen beats per minute. *Id.* at 182; Ex. 12 at 33 (showing heart rate increase from seventy-one BPM when seated to eighty-eight BPM when standing). Dr. Gillespie nonetheless found this increase sufficient to seek further testing, so he referred Petitioner to Dr. Noll, an electrophysiologist, for formal confirmation. Tr. at 172–74, 182. He did not recall, however, whether Petitioner was again symptomatic after standing, although he surmised she likely was (as the record suggested that he terminated the sit-stand test prematurely). *Id.* at 171–72, 180.

On cross examination, Dr. Gillespie was asked about the appropriateness of relying on orthostatic readings taken from a sit-stand test as opposed to a tilt table test. He acknowledged that the tilt table test was preferable for diagnosing POTS, but argued nevertheless that a sit-stand test was an adequate alternative, especially when dealing with a patient like Petitioner, whose symptoms had previously prevented her from completing her first such test in 2011. Tr. at 178–79. He also allowed that Petitioner's medical history allowed for the "understandable concern" that her post-vaccination symptoms were connected to her pre-vaccination state (and in particular admitted that deconditioning could exacerbate orthostatic intolerance symptoms), but otherwise felt it unlikely that anxiety explained Petitioner's overall condition. *Id.* at 174, 176. Overall, Dr.

Gillespie emphasized that his POTS diagnosis was derived from Petitioner's actual presentation at his two visits with her in 2014 (almost three years after vaccination). *Id.* at 177.

4. Dr. Yehuda Shoenfeld

Dr. Shoenfeld was the sole non-treating medical expert who testified on Petitioner's behalf in this case. He offered a theory explaining how the Hep B vaccine could cause POTS and CFS, as well as an explanation of how the vaccine specifically caused Mrs. Yalacki's claimed illnesses.

Besides his oral testimony, Dr. Shoenfeld provided a total of five reports on behalf of Petitioner, modifying his causation theory over time in response to my preliminary determinations about the theory's credibility. *See generally* Ex. 18, filed Dec. 22, 2015 (ECF No. 29-1) ("Shoenfeld First Rep."); Ex. 111, filed Mar. 28, 2016 (ECF No. 33-1) ("Shoenfeld Second Rep."); Ex. 116, filed Jan. 30, 2017 (ECF No. 53-1); Ex. 117, filed Aug. 31, 2017 (ECF No. 57-1) ("Shoenfeld Fourth Rep."); Ex. 127, filed Nov. 29, 2017 (ECF No. 76-1) ("Shoenfeld Fifth Rep.").[17] In particular, although Dr. Shoenfeld initially proposed a theory he has embraced in other cases termed "autoimmune/inflammatory syndrome induced by adjuvants" ("ASIA") to explain causation, he largely abandoned it in response to my expressed skepticism of its reliability (as discussed below). *Compare* Shoenfeld First Rep. at 12–13 (discussing applicability of ASIA theory to Petitioner's case) *with* Shoenfeld Fourth Rep. at 13–14 (explaining theory of causation based solely on mechanism of molecular mimicry and with no discussion of ASIA).

Dr. Shoenfeld, an internist and clinical immunologist, identifies himself as the head of the Center for Autoimmune Diseases, which he founded at the Sheba Medical Center in Israel. Shoenfeld First Rep. at 1; Tr. at 9. He holds the Laura Schwarz–Kipp Chair for Research of Autoimmune Diseases at Tel Aviv University and has published numerous peer-reviewed articles and books, primarily in the field of autoimmune and rheumatic diseases. Shoenfeld First Rep. at 1; Tr. at 9. He serves on the editorial board of thirty-two journals in the field of autoimmunity, and regularly speaks at conferences centered on autoimmune issues. Shoenfeld First Rep. at 1.[18]

[17] Petitioner also offered a sixth expert report from Dr. Shoenfeld in November 2018, ten months after the conclusion of the hearing, and three months after both sides had filed post-trial briefs. *See* Ex. 134, filed Nov. 19, 2018 (ECF No. 97-1). I struck the report from the record because it was (a) untimely, (b) not filed with my permission or at my request, and (c) was not based on newly-discovered or published literature that could *itself* not have been filed in a timely fashion. Order at 2–3, dated Dec. 7, 2018 (ECF No. 101). However, even if I had allowed the report into evidence, it would not have appreciably aided Petitioner in meeting her burden of proof. The untimely report addresses a single issue: cross-reactivity between the Hep B vaccine and CFS/POTS based upon possible homology based on a six-amino acid chain rather than five. Ex. 134 at 1. However, the reliability and plausibility of Petitioner's causation theory writ large does not turn on this point in the slightest; for even if accepted as true, it does not make it more likely than not that any components of the Hep B vaccine *could* initiate any autoimmune or otherwise aberrant immune response sufficient to cause CFS or POTS, for the numerous reasons discussed below.

[18] On cross-examination, Respondent devoted many questions to undermining Dr. Shoenfeld's credentials, reported titles, and research topics and practices. *See* Tr. at 148–64. For example, Respondent sought Dr. Shoenfeld's acknowledgement that he is not actually employed at Sheba Hospital in Tel Aviv (*id.* at 148–50), that a paper he wrote

However, Dr. Shoenfeld does not have specialized expertise in the study or treatment of either POTS or chronic fatigue, although he did assert that he had published articles on both. Tr. at 9.

At hearing, Dr. Shoenfeld testified about Petitioner's claimed diagnoses of POTS and CFS, as well as about possible causal connections between the Hep B vaccine and the two conditions. Although the opinions he offered differed slightly when discussing each diagnosis, in either case he opined that the Hep B vaccine could (and in this case did) cause the relevant illness via some kind of autoimmune process. Dr. Shoenfeld explicitly termed POTS a "classic autoimmune disease" that could be vaccine-caused. Tr. at 13. CFS, by contrast, only "smell[s] of autoimmunity," given the lack of direct scientific support for the position that it is autoimmune, although he nevertheless proposed it was "probably" autoimmune in origin as well. *Id.* at 133–35, 208.

Dr. Shoenfeld began his testimony with a discussion of POTS, characterizing it as featuring a rapidly increased heart rate when a person stands due to a rush of blood to the head. Tr. at 12–13. He explained further that POTS reflects the working of the autonomic nervous system, which controls body functions automatically, without will or knowledge on the part of the individual at issue. *Id.* at 13. Several different triggers can bring about POTS, including viruses, bacteria, or vaccines containing adjuvants. *Id.* at 17–18. The primary diagnostic criteria for POTS, in Dr. Shoenfeld's view, is an increased heart rate of at least thirty BPM upon moving from a seated or recumbent position to standing. *Id*. at 25. He added, however, that some individuals may experience a heart rate increase just shy of thirty BPM but still warrant the POTS diagnosis, especially if the heart rate increase is accompanied by presyncope.[19] *Id.* at 29.

Dr. Shoenfeld also briefly discussed his understanding of the two methods of diagnosing POTS: the tilt table test and the sit-stand test. Tr. at 25–26. He characterized the tilt table test as

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on the ASIA theory's applicability to the HPV vaccine was later retracted (*id.* at 162–64), that he appears to serve on the advisory board of an anti-vaccination group (the group's website lists him as a board member) (*id.* at 154–56), and that the same anti-vaccination group appears to have funded some of his research (*id.* at 156–62).

These attacks were somewhat successful. Because Dr. Shoenfeld's medical expertise on immunological matters has been demonstrated in numerous prior Vaccine Program cases (including cases I have heard personally), evidence of personal bias or misrepresentations in his CV established by such questioning *in this case* (which were not established to be intentional *per se*) is not enough for me to find him unqualified to testify. Nevertheless, Dr. Shoenfeld's combative response to this questioning, coupled with outright evasiveness in responding to certain questions regarding his background, did reduce his overall credibility as a truthful witness.

In any event, my ultimate decision in this case turns less on Dr. Shoenfeld's personal credibility and more on the overall unreliability of the scientific theory he offered when weighed against the strength of Respondent's expert evidence. Dr. Shoenfeld is advised, however, to correct any errors in his CV of this nature if he wishes to maintain his professional credibility as a Vaccine Program expert in future proceedings.

[19] Presyncope is a feeling of faintness or lightheadedness. *Balance Problems*, Mayo Clinic (May 17, 2018), https://www.mayoclinic.org/diseases-conditions/balance-problems/symptoms-causes/syc-20350474.

"elegant," but deemed the sit-stand test "much more effective" and "more accurate." *Id.* at 25–26, 205. In his view, a positive sit-stand test result (revealing a heart rate increase of thirty BPM or more) would strongly confirm a POTS diagnosis, but a negative result would not rule out a POTS diagnosis. *Id.* at 28. He went so far as to disparage the tilt table test, saying, "[w]hat is a tilt test? I mean, it has a name, and it may impress lay people who are not in the medical field." *Id.* at 234.

In Dr. Shoenfeld's opinion, POTS is an autoimmune disease, a viewpoint he stated is supported by "several papers." Tr. at 14–15. Indeed, when questioned as to whether it was *always* autoimmune in origin, he proposed that "most if not all POTS . . . cases are autoimmune [in] origin until proven otherwise." *Id.* at 227. Autoimmune disease, he explained, "is a condition in which the immune system . . . turns toward our own body constituents." *Id.* at 11. Such diseases are a downside to an otherwise evolutionarily advantageous "aggressive immune system," and he noted that, as women have more aggressive immune systems than men, autoimmune diseases affect women at a rate almost ten times higher than they do men. *Id.* at 11–12. Dr. Shoenfeld explained that an antibody generated in reaction to a foreign antigen (whether presented by a live virus or vaccine component) may be identified as pathogenic if it is directed at and affects a "functional epitope," or self protein structure in the body, resulting in harm or dysfunction. *Id.* at 15–16. The best way to identify a pathogenic autoantibody, in his view, is to inject it into a healthy specimen to see whether it causes disease, though he also noted that pathogenic autoantibodies can be identified via in utero transfer from pregnant women to their children. *Id.* at 16.

Based on review of the record in this case, Dr. Shoenfeld opined that Petitioner in fact suffered from POTS. Tr. at 57. In support, he referenced the results of her various sit-stand tests, concluding that her heart rate increase of twenty-eight BPM, though admittedly below the diagnostic criteria of thirty BPM, was nonetheless indicative of POTS. *Id.* at 27. This was so even though some of Mrs. Yalacki's testing was not completed, since the records (for example, from Dr. Gillespie's examination) revealed that testing was halted out of concern that Mrs. Yalacki might faint. *Id.* at 51, 54. He also cited POTS diagnoses by three treating cardiologists, the fact that Petitioner lost consciousness several times in the months following vaccination, and a high recorded heart rate in a Holter monitor test as a basis for his opinion. *Id.* at 36–37, 57. By contrast, he found her initial, negative tilt table test from 2011 to be insignificant, despite the fact that it was performed closer in time to her receipt of the Hep B vaccine. *See id.* at 40.

Turning to the question of whether Petitioner's alleged case of POTS resulted from an autoimmune process, Dr. Shoenfeld simply (and in a somewhat circular fashion) stated that the fact that she *had* the disease was strong evidence of its autoimmune nature. Tr. at 233. Because he believes that POTS is an autoimmune disease, it follows that it has an autoimmune etiology. *Id.* He did, however, cite certain literature filed in this case as supporting his contention that POTS could be autoimmune. Shoenfeld First Rep. at 8 (citing M. Thieben, et al., *Postural Orthostatic Tachycardia Syndrome: The Mayo Clinic Experience*, 82 Mayo Clinic Proc. 308 (2007), filed as

Ex. 43, Mar. 31, 2016 (ECF No. 34) ("Thieben")). Thieben was a retrospective study of 152 POTS patients seen at the Mayo Clinic over eleven years, and considered the data and test results obtained during treatment. Thieben hypothesized that a particular autoantibody (the ganglionic acetylcholine receptor) was associated with neuropathic cases of POTS, although by its own terms the article does *not* propose or embrace Dr. Shoenfeld's contention that POTS is in *all* cases an autoimmune disease. Thieben at 308.

Consistent with the above discussion of autoantibodies, Dr. Shoenfeld proposed that the Hep B vaccine could cause POTS through the mechanism of molecular mimicry. Tr. at 19–20. As he explained, because of sequential/structural similarities between peptide amino acid sequences within the viral protein components of vaccines and self protein structures in the human body, antibodies produced in response to a vaccine might also mistakenly attack the self structures, thereby turning the antibodies into autoantibodies and causing harm in the form of an autoimmune disease. *Id.* at 20. He emphasized the role of the alum adjuvant in vaccines in aiding this process, as it can drastically increase the production of autoantibodies. *Id.* at 21.[20] In this case, Dr. Shoenfeld maintained that a particular peptide sequence in the Hep B vaccine—LLLCL—has homology with "myelin sheets of nerves," and could therefore result in an autoantibody response triggered by the vaccine. *Id.* at 23, 213–18.[21] CFS, he later noted, could also be vaccine-caused through the same mechanism. *Id.* at 142, 209.

Despite the above, Dr. Shoenfeld acknowledged limitations to his assertions that Petitioner's POTS was autoimmune in nature. Thus, he conceded that Mrs. Yalacki was never tested for the specific autoantibodies known to be associated with POTS. Tr. at 231–32. In addition, Dr. Shoenfeld maintained that Mrs. Yalacki had undergone plasmapheresis,[22] a treatment directed at autoimmune diseases and which purportedly brought one autoimmune POTS patient into remission as identified in a scientific study. *Id.* at 17; Shoenfeld Fifth Rep. at 4 (citing J. Hendrickson, et al., *Complex Regional Pain Syndrome and Dysautonomia in a 14-Year-Old Girl Responsive to Therapeutic Plasma Exchange*, 31 J. Clinical Apheresis 368 (2016), filed as Ex. 128, Nov. 30, 2017 (ECF No. 77-1)). But he could not point to any medical records establishing that

[20] Dr. Shoenfeld did, however, attempt to maintain in so arguing that he was *not* re-introducing his ASIA theory through a back door. *See* Tr. at 122–24.

[21] Tangential to his main theory, Dr. Shoenfeld also referenced the condition of small fiber neuropathy—an illness he acknowledged Petitioner has not been diagnosed with—as nevertheless relevant, given that it purportedly proceeds by the same molecular mimicry mechanism proposed in this case. Shoenfeld First Rep. at 22; Tr. at 209–11. He did, however, maintain that it is common for individuals suffering from small fiber neuropathy also to have CFS. Tr. at 212 (discussing M. Martinez-Lavín, *Hypothesis: Human Papillomavirus Vaccination Syndrome—Small Fiber Neuropathy and Dysautonomia Could Be its Underlying Pathogenesis*, 34 Clinical Rheumatology 1165 (2015), filed as Ex. 86, Mar. 31, 2016 (ECF No. 34)).

[22] The process of drawing blood, removing the plasma therefrom, and replacing it with another substance, such as albumin or type-specific fresh frozen plasma. *Dorland's* at 1456.

Petitioner *in fact* received plasmapheresis, and I have found in the medical record no evidence that such treatment occurred. Tr. at 17, 203–04. When faced with the absence of such evidence, Dr. Shoenfeld again resorted to the same "heads I win, tails you lose" logic that he embraced when asked about the significance of negative orthostatic testing results in Petitioner's history, stating that "[i]f it happened, it supports; if it didn't happen, it does not exclude." *Id.* at 204.

Another deficiency in Dr. Shoenfeld's contentions concerning the autoimmune character of POTS was highlighted by his attempt to explain precisely *how* autoantibodies allegedly produced in response to the Hep B vaccine would cause POTS. Dr. Shoenfeld pointed to an item of literature establishing that the gene that codes for norepinephrine transport plays a role "in regulating the orthostatic reaction," with the antibodies presumably interfering in some way with the norepinephrine transporter, affecting its function and resulting in POTS. Tr. at 223, 230 (discussing J. Shannon, et al., *Orthostatic Intolerance and Tachycardia Associated with Norepinephrine-Transporter Deficiency*, 342 New England J. Med. 541 (2000), filed as Ex. S, Jan. 17, 2018 (ECF No. 83-1) ("Shannon")). Shannon compared findings between an individual known to have orthostatic intolerance and her twin. Shannon at 541. But Dr. Shoenfeld acknowledged that Shannon does not establish that this same transporter *is* harmed in the manner alleged, nor does the article speak about the relevant autoantibodies. Tr. at 223, 225. Indeed, he expressed doubt that the target of the autoantibody attack could even be identified (*id.* at 229 ("you can never know where it might affect")), and ultimately relied on the reflexive logic of the existence of Petitioner's alleged POTS as evidence that the autoimmune process he proposed had in fact occurred. *Id.* at 221.

Dr. Shoenfeld also maintained that, based upon his review of the medical records, Petitioner had CFS.[23] He began with review of the CDC diagnostic criteria for CFS, noting that the condition is associated with orthostatic intolerance. Tr. at 129–30. In his view, however, some criteria (like fatigue) are more significant to the diagnosis than others (such as memory loss). *Id.* at 144. He acknowledged as well that depression can overlap with CFS, although he disputed that the existence of depression is an exclusionary factor, and in fact maintained that a person with depression would be susceptible to CFS, especially after vaccination. *Id.* at 116, 117, 131.

In his discussion of CFS, Dr. Shoenfeld conceded that the disease is not widely considered to be autoimmune, but insisted that it "has an autoimmune flavor." Tr. at 135. He also admitted that no pathogenic autoantibodies have been identified in relation to CFS, but argued that it is his expectation that such autoantibodies will likely be discovered eventually, given CFS's "association with other autoimmune diseases," its "close overlap" with POTS, and the unique prevalence of

[23] It is somewhat unclear whether Petitioner maintains that she suffers from *both* conditions or merely pleads them as alternative injuries equally supported by the record. In her post-hearing brief, Petitioner states that she suffered from "CFS and/or POTS." Pet'r's Post-Hr'g Br. at 5. Regardless, Dr. Shoenfeld expressed the opinion that both could have a similar autoimmune character, as well as a similar vaccine-induced origin. Tr. at 142.

CFS among women (similar to other autoimmune diseases). *Id.* at 134–35. He also noted that, as with other autoimmune diseases, CFS patents can be subject to relapse and remission. *Id.* at 132.

Part of Dr. Shoenfeld's testimony involved a chronological review of Mrs. Yalacki's post-vaccination medical history, allowing him to point out times and occurrences that he maintained were consistent with his causation theory. First, looking to early June 2011, he opined that onset of POTS or CFS did not occur within ninety minutes after vaccination, contrary to Petitioner's statements to treaters. Rather, he characterized Petitioner's state on June 2nd and 3rd as reflective of a post-vaccination malaise common to any individual who receives a vaccine. Tr. at 117–18 (noting that vaccine package insert anticipates some malaise after vaccination), 120, 124–25.

Not long thereafter, however, Petitioner experienced onset of CFS and/or POTS—although Dr. Shoenfeld equivocated greatly as to the precise date of onset. Thus, he seemed to identify June 6, 2011—four days post-vaccination—as the date Petitioner's CFS began, based on medical record evidence of a significant worsening of her fatigue that he distinguished from her immediately-reported reaction. Tr. at 136–37, 141–42, 198. He deemed such a four-day timeframe medically acceptable, given that this was third Hep B dose Petitioner had received, prompting a "challenge-rechallenge" effect[24] more rapid (in generating antibodies responsive to vaccination) than an individual would experience if the vaccine were being administered for the first time. *Id.* at 59, 60. Subsequently, the medical record revealed ongoing progression of Petitioner's fatigue that Dr. Shoenfeld deemed corroborative of her later CFS diagnoses in the following year and thereafter. *Id.* at 40, 138, 139.

In some of his prior written reports, however, Dr. Shoenfeld embraced Petitioner's *immediate* malaise reaction (within two hours of vaccination) as a medically acceptable timeframe for onset of her POTS and/or CFS. Shoenfeld First Rep. at 14; Shoenfeld Fourth Rep. at 13. When confronted with this discrepancy, Dr. Shoenfeld countered that his understanding of the case had evolved after closer study. Tr. at 185, 199. At the same time, he maintained that Petitioner's onset may have begun within ninety minutes after vaccination (as the records indicate she reported to treaters), emphasizing that the only important consideration was the fact that onset post-dated vaccination. *Id.* at 191 ("[t]he start might have been immediately after the vaccine, the start might have been several days after the vaccine, the start might have been also several weeks after the vaccine . . . we cannot know. None of us can know. We can only assume that the vaccine caused it"), 192, 202 (agreeing with Respondent that "no objective evidence" existed establishing when Petitioner's nonspecific vaccine-induced malaise ended and her CFS and/or POTS began).

[24] A "challenge-rechallenge" effect occurs "when a patient who had an adverse reaction to a vaccine suffers worsened symptoms from an additional injection of the vaccine." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1322 (Fed. Cir. 2006). In this case, of course, the eleven-year gap between when Mrs. Yalacki last received the Hep B vaccine and her June 2011 dose is simply too long to give consideration to this argument (which Dr. Shoenfeld otherwise did not linger on in his testimony).

With regard to onset of Petitioner's POTS, Dr. Shoenfeld stressed that evidence of dizziness was more probative than fatigue (although because CFS and POTS had some symptomatic overlap, fatigue could be a POTS symptom). Tr. at 190, 194. However, he was reluctant to attribute reports of dizziness the day after vaccination as onset of Petitioner's POTS. *Id.* at 194–96. Rather, Dr. Shoenfeld seemed more comfortable referencing symptoms that Petitioner displayed a little more than one month later (beginning July 8, 2011) as "classically" proof of orthostatic intolerance, with a fainting incident reported by Mrs. Yalacki to treaters on July 28, 2011 as further evidence of her POTS. *Id.* at 32–33. In August and September of that year, Petitioner's orthostatic problems became even more evident, and were subsequently confirmed by heart rate monitor testing. *Id.* at 34–36, 38–39 (deeming significant Dr. Abruzzo's statement from September 2011 that Petitioner might have an "autonomic neuropathy").[25]

Dr. Shoenfeld disputed the existence of reasonable alternative explanations for Petitioner's symptoms. He noted that treaters had early on excluded the possibility of a viral infection, ongoing inflammation, or some similar cause for her reaction and fatigue. Tr. at 126–28. However, he was more conclusory when discussing Petitioner's overall history, including the ample evidence of Petitioner's preexisting symptoms, which included not only fatigue but considerable mental health issues that could have related to her post-vaccination condition. *See, e.g.*, *id.* at 38–39 ("[t]here is only one time, I believe, that in that file [Petitioner's medical record] the word 'tired' was mentioned before the hepatitis B"), 140 (maintaining that there is "no comparison" between Petitioner's pre- and post-vaccination symptoms relevant to her purported CFS or POTS diagnoses).

B. *Respondent's Witnesses*

1. Dr. Philip Low

Dr. Low filed two reports in this case and also testified at hearing. *See* Ex. H, filed June 30, 2016 (ECF No. 42-7); Ex. N, filed Oct. 16, 2017 (ECF No. 64-6). Dr. Low offered the opinion that Mrs. Yalacki suffers from "severe debilitating deconditioning," and that any associated mild orthostatic intolerance she has experienced was solely the product of that deconditioning (which in turn stemmed from her demonstrated anxiety). Tr. at 259, 299.

As noted in his curriculum vitae ("CV"), Dr. Low received his medical and research doctorate degrees from the University of Sydney in Australia. Ex. I at 1, filed June 30, 2016, ECF No. 43-7 ("Low CV"); Tr. at 249. He completed a fellowship in internal medicine with the Royal Australian College of Physicians, as well as a neurology residency at the Mayo Clinic in Rochester,

[25] Dr. Shoenfeld also attempted to diminish record proof that undermined or contradicted a POTS diagnosis. Thus, when asked about determinations in February 2013 by Dr. Rollins that Petitioner did not likely have POTS given the orthostatic readings she obtained, Dr. Shoenfeld demurred, arguing (as before in his testimony) that while positive results confirmed his preferred diagnosis, negative tests did not necessarily exclude it. Tr. at 207–08.

Minnesota. Low CV at 1–2. Currently, Dr. Low serves as a Professor of Neurology at the Mayo Clinic Medical School. *Id.* at 3. During his time at Mayo, Dr. Low has served in various departmental and academic capacities, including as Director of the Neuroscience Laboratory, Director of the Autonomic Reflex Laboratory (which he founded), and Chairman of the Division of Clinical Neurophysiology. Low CV at 3–4; Tr. at 254. Dr. Low has co-authored over four hundred items of literature in the field of autoimmunity, including many articles on POTS, antibody-mediated autoimmune neuropathy, and orthostatic intolerance. Low CV at 9–50; Tr. at 258. Indeed, he is a senior author or author in roughly half of the articles on POTS referenced in Dr. Shoenfeld's reports and filed by Petitioner. Tr. at 271. He has served on the editorial boards of multiple journals centered on autonomic and nervous system research. Low CV at 4.

Over the past forty years, Dr. Low's time has been divided evenly between patient practice and research. Tr. at 255–56. During his clinical practice, which is focused on autonomic disorders, Dr. Low estimates that he sees twenty to thirty patients per week. *Id.* at 256. He has treated many patients with POTS, small fiber neuropathy, orthostatic intolerance, CFS, autoimmune disorders, and autoimmune neuropathies. *Id.* at 256–57.

At hearing, Dr. Low provided extensive background information on the autonomic nervous system. As he explained, the autonomic system controls the heart rate and blood pressure, stabilizing both without conscious effort as people move between different postures and positions. Tr. at 260. He defined terms relevant to autonomic nervous system dysfunction, including autonomic neuropathy ("neuropathy due to structural damage of autonomic fibers," with many apparent and readily-identified symptoms). *Id.* at 261. Tests exist to assess possible damage to the autonomic system, which Dr. Low himself has helped to develop. *Id.* at 264. He was dismissive of the term *dysautonomia*, however, calling it an "almost useless term" that is frequently employed as a catch-all when a treater "can't think of something better" to precisely explain the source of an orthostatic problem. *Id.* at 261.

Orthostatic intolerance, Dr. Low explained, is an umbrella term for conditions in which "when you stand up, you feel bad, and if you sit down or lay down, you no longer feel bad." Tr. at 262–63. He distinguished between three subcategories of orthostatic intolerance: orthostatic hypotension, in which an individual's blood pressure drops when she stands up, unaccompanied by a significant change in heart rate; POTS, in which the heart rate increases but blood pressure remains unchanged when an individual stands up; and syncope, in which both the heart rate and blood pressure undergo a delayed and sudden drop, often leading to fainting. *Id.* at 263. POTS, Dr. Low stated, is *not* usually caused by damage to the autonomic nervous system. *Id.* at 270. CFS can be associated with POTS, he noted, though the existence of chronic fatigue is not integral to a POTS diagnosis. *Id.*

Dr. Low also provided a detailed explanation of deconditioning and its relationship to orthostatic intolerance and POTS. He deemed it very common for POTS (and other forms of orthostatic intolerance) to be the result of physical deconditioning,[26] whether due to inactivity or environmental demands. Tr. at 280–81. He described a study of his own, in which he found that ninety percent of a set of POTS patients had "laboratory-proven" deconditioning. *Id.*; *see also* A. Parsaik, et al., *Deconditioning in Patients with Orthostatic Intolerance*, 79 Neurology 1435 (2012), filed as Ex. H Tab 7, June 30, 2016 (ECF No. 43-2) (Dr. Low as co-author). He also referenced studies involving astronauts upon their return to earth as confirming the effects of the deconditioning they experienced after spending long amounts of time in space. Tr. at 281. Accordingly, in Dr. Low's view, deconditioning can cause POTS (although it more commonly leads to a "lesser degree" of orthostatic tachycardia). *Id.* at 281–82. He estimated that the negative effects of deconditioning could manifest after just two weeks of physical inactivity. *Id.* at 282.

Dr. Low emphatically contested Dr. Shoenfeld's view that POTS is predominantly autoimmune in nature, supporting his position with experiences from his own research at Mayo. Tr. at 271. Dr. Low agreed that there does exist a form of autonomic neuropathy involving a single type of ganglionopathy-associated autoantibody, and that Thieben had observed that six of forty-two studied subjects (or approximately fourteen percent) tested positive for this antibody. *Id.* at 271–72; Thieben at 311, 313. This kind of neuropathy involves structural damage to the autonomic nervous system, resulting in POTS-like symptoms as well as many other symptoms *not* present in this case (or in most POTS cases for that matter). Tr. at 272, 303–04 (listing loss of blood pressure control, loss of bladder control, loss of ability to breathe, and tissue injury as other clinical indicia of existence of autoimmune-mediated autonomic neuropathy). It would also be characterized by high levels of the relevant autoantibody. *Id.* at 272.

But Dr. Low indicated that his own extensive research into POTS and the autonomic nervous system had led him to question the prevalence of autoimmune-caused autonomic neuropathy. As he explained, his study and treatment of POTS patients had generally revealed "multiple antibodies at low titers." Tr. at 272. In addition, Dr. Low noted that since Thieben's publication over ten years ago, researchers at Mayo had looked more closely into the correlation between the autoantibodies it first observed and POTS but found "zero relationship of titer to autoimmune failure." *Id.* As a result, Dr. Low today does not routinely test POTS patients for particular autoantibodies, "because we have not been able to demonstrate any causative antibody." *Id.* at 274. He also added that, unlike diseases widely understood to be autoimmune (for example, Guillain-Barré syndrome), POTS cannot be effectively treated with immunosupressants or other immune-mediating therapies like plasmapheresis. *Id.* at 274–75.

[26] Deconditioning is "a change in cardiovascular function after prolonged periods of weightlessness." *Dorland's* at 475.

There are certain clinical procedures widely recognized as appropriate for diagnosing POTS. Tr. at 264–66. Contrary to Dr. Shoenfeld, Dr. Low opined that the tilt table test is "essential for the diagnosis of POTS," and that a consensus view exists in the medical community that this is the case. *Id.* at 265, 297–98, 307. He deemed the sit-stand test, by contrast, "totally inadequate" to make a formal diagnosis of POTS, although he allowed that it was a reasonable tool for treaters to use in assessing if a potential POTS diagnosis was worthy of further investigation. *Id.* at 305–06. The sit-stand test is unstandardized, and necessarily requires a patient to contract her muscles (thereby affecting the heart rate reading), which the tilt table test largely avoids. *Id.* at 266–67, 305. He conceded that the tilt table test is not perfect, however, and that more accurate results could be obtained by performing a "parachute tilt," which entails the use of a harness. *Id.* at 267. He also noted that a Holter monitor is not a useful diagnostic for POTS, as it simply measures heart rate over time and does not discount the natural surges in heart rate that many people experience intermittently, especially when they suffer from anxiety. *Id.* at 270. Besides the tilt table test, Dr. Low routinely measures autonomic function to test for POTS, and also measures plasma norepinephrine levels in the patient's blood, both while sitting and standing. *Id.* at 269, 296–70.

Dr. Low reiterated that a measured heart rate increase of at least thirty BPM in a standardized tilt table test is a critical diagnostic feature of POTS. Tr. at 301. He added, however, that this is a "very low bar," and that in addition to the sharp increase in heart rate, a POTS patient would typically present with a high *absolute* heart rate as well—typically above 120 BPM. *Id.* at 302. This type of heart rate increase and high absolute heart rate would be consistent over multiple readings for a POTS patient, he noted. *Id.* at 301.

Based on the above, his own personal knowledge, and his review of the medical records, Dr. Low opined that Petitioner did not likely have POTS in 2011 or 2012. Tr. at 283. Her tilt table test (performed in September 2011) lasted for thirteen minutes, longer than the standard ten, but her heart rate increased by only ten BPM. *Id.* (discussing Ex. 5 at 84). Records from that same visit also did not reflect other symptoms of orthostatic intolerance essential for a POTS diagnosis. *Id.* at 283–84. Otherwise, throughout Petitioner's medical records over the relevant time period, there were "too many normal type recordings" of her heart rate to substantiate a POTS diagnosis. *Id.* at 301. In addition, and although not measured until 2013, Mrs. Yalacki's plasma norepinephrine levels also tested at normal levels. *Id.* at 278. At most, she experienced intermittent mild orthostatic intolerance attributable to deconditioning. *Id.* at 293–94, 301. He also noted that the many heart rate increase readings seen in the medical record and cited to as proof of POTS could equally be attributed to Petitioner's demonstrated long-standing anxiety. *Id.* at 296.

To substantiate his conclusions, Dr. Low highlighted numerous aspects of Petitioner's medical record. In the years before receiving the Hep B vaccine, Petitioner showed signs of an overactive sympathetic nervous system (dizziness, nausea, etc.) on several occasions, indicating

possible anxiety. Tr. at 279–80 (discussing Ex. 1 at 9, 70 (June and October 2008 records)). He deemed it common in "patients who have significant deconditioning" to display such symptoms. *Id.* at 280. Dr. Low went on to characterize Petitioner's post-vaccination symptoms beginning June 2011 as a continuation of such prior symptoms. *Id.* And he took particular note of some of the neurologic evaluations Petitioner received in 2012 and 2013. Thus, Dr. Seibert deemed it unlikely in November 2012 that Mrs. Yalacki was suffering from "autonomic dysreflexia" (which Dr. Low characterized as featuring "storms" in which the autonomic nervous system "goes crazy"). *Id.* at 293 (discussing Ex. 2 at 537). Dr. Rollins similarly doubted that the existing test results and record at the time (winter 2013) supported a POTS diagnosis. Tr. at 293 (discussing Ex. 2 at 636).

Dr. Low also reviewed some of the cardiologic exams and associated orthostatic testing Petitioner underwent in the years after her receipt of the Hep B vaccine, concluding from these records that there was not strong evidence supporting a POTS diagnosis. For example, he noted that during Petitioner's visits to Dr. Betkowski in March 2013 (almost two years after receiving the Hep B vaccine), testing revealed a blood pressure *drop* on the sit-stand test—a determination inconsistent with a POTS diagnosis, even if Petitioner's heart rate did increase (which could, in Dr. Low's view, simply reveal a "healthy heart"). Tr. at 268–69, 286 (discussing Ex. 2 at 667). He was similarly dismissive of the orthostatic readings obtained at an April 2013 visit with Dr. Betkowski, noting that while tests revealed a "generous heart rate response," they similarly showed a drop in blood pressure that would not be consistent with POTS. *Id.* at 286–87 (discussing Ex. 2 at 702).

Dr. Gillespie's examinations of Petitioner in 2014 (which, as noted above, Dr. Gillespie discussed at hearing) were no more persuasive to Dr. Low of the accuracy of the POTS diagnosis. He characterized the heart rate increase that Dr. Gillespie measured via a sit-stand test during Petitioner's April 2014 exam (from seventy-one to eighty-eight BPM) as "unimpressive," and otherwise "very typical of the changes one sees with deconditioning." Tr. at 288–89 (discussing Ex. 12 at 6). Indeed, the fact that Petitioner had been able to stand for a lengthy period of time during this exam to remeasure her standing blood pressure was evidence that she was in fact "orthostatically tolerant" as of that time. *Id.* at 288. Dr. Gillespie's findings at Petitioner's May 2014 visit were also in Dr. Low's view unsupportive of a POTS diagnosis, as she experienced a fairly normal heart rate increase. *Id.* at 298 (discussing Ex. 12 at 33–34). And at another treater's visit in July 2014, Petitioner displayed a modest standing absolute heart rate of 106 BPM, which Dr. Low deemed insufficient to suggest POTS. *Id.* at 290 (discussing Ex. 15 at 203). At best, the heart rate increase Petitioner displayed at this time indicated the need for a repeat of the negative tilt table test she had received in 2011. *Id.* at 290–91.

Besides noting the deficiencies in the medical record for a POTS diagnosis, Dr. Low testified that he saw no evidence in that same record supporting the conclusion that Petitioner suffered from an autoimmune-mediated autonomic neuropathy that could have caused her POTS

symptoms. The medical record, he opined, did not suggest that Mrs. Yalacki had ever suffered any injury to autonomic structures, nor did she display the secondary symptoms (in addition to orthostatic intolerance suggestive of POTS) that would reveal the existence of such damage, such as loss of bladder control or breathing difficulties. Tr. at 294. There is also no evidence in the record that Petitioner tested positive for the autoantibody discussed in Thieben (and although Petitioner may not have undergone such testing, Dr. Low suggested that this was likely due to the fact that treaters saw no need to do so). *Id.* at 295.

Finally, Dr. Low addressed some specific components of Petitioner's causation theory. In his understanding of Dr. Shoenfeld's testimony, Dr. Shoenfeld had proposed that an "adrenergic antibody," presumably produced in response to the Hep B vaccine, was the most likely mechanistic causal element in triggering POTS. Tr. at 272. But literature offered to support this contention did not involve an actual measurement of the antibody in question in humans. *Id.* (discussing H. Li, et al., *Autoimmune Basis for Postural Tachycardia Syndrome*, J. Am. Heart Ass'n 1 (2014), filed as Ex. 58, Mar. 31, 2016 (ECF No. 34) ("Li")). Rather, the Li study evaluated the effect of an injection of blood serum from fourteen POTS patients into animals on arteriole contractibility, concluding that POTS could have an autoimmune pathology. Tr. at 272–73; Li at 9. Dr. Low did not accept this finding, however, interpreting Li to be observing merely "a secondary phenomenon that occurs in people who have sympathetic activity, either because of the disease, or because of treatment," *not* that the antibody itself was associated with causing POTS. Tr. at 273–74.

Dr. Low also criticized Dr. Shoenfeld's reliance on Shannon, which, as noted above, looked at the norepinephrine transporter responsible for uptake and management of adrenaline in the blood based on a single-patient evaluation, and which Dr. Shoenfeld argued was evidence of a plausible antigenic target for his theorized autoimmune attack. Tr. at 275–76 (discussing generally Shannon). Normally, when a person stands, the sympathetic nerve is activated, causing the release of norepinephrine (a kind of adrenaline specific to blood vessels), with some norepinephrine interacting with a receptor while the rest is taken back up by the transporter. *Id*. at 276. Shannon considered a single individual who experienced dysfunction of the transporter (likely due to genetic mutation) in comparison to her healthy twin, concluding that the excess norepinephrine that was not taken back up due to transporter failure resulted in tachycardia. *Id.* (discussing Shannon at 542–44). But Dr. Low questioned the significance of Shannon, noting first that it involved a single individual, and second that Mrs. Yalacki's *own* blood norepinephrine levels were tested in March 2013 and found to be normal, rendering Shannon's findings immaterial. Tr. at 276–77 (discussing Ex. 3 at 7), 278 (characterizing the norepinephrine amounts measured in Petitioner as "not the value you would expect in someone with norepinephrine transporter blockage").

2. Dr. Peter Donofrio

Peter Donofrio, M.D., provided two written reports on Respondent's behalf and testified at hearing. *See* Ex. A, filed July 27, 2015 (ECF No. 25-1); Ex. O, filed Oct. 16, 2017 (ECF No. 64-9). Dr. Donofrio offered the opinion that Mrs. Yalacki did not have CFS, and that any post-vaccination symptoms she did experience were most likely attributable to her prior documented mental health problems and anxiety.

As reflected in his CV, Dr. Donofrio received his B.S. at the University of Notre Dame in Indiana, followed by his M.D. at Ohio State University in Columbus. Ex. B at 1, filed July 27, 2015 (ECF No. 25-8) ("Donofrio CV"). He completed a three-year internal medicine residency at Good Samaritan Hospital in Cincinnati, Ohio, followed by a three-year neurology residency at the University of Michigan. *Id.* at 2. He also completed a neuromuscular fellowship at the University of Michigan. *Id.* Dr. Donofrio holds board certifications in neurology, nerve conduction studies, electromyography, and neuromuscular disorders. Tr. at 309. He currently serves as a professor of neurology at Vanderbilt University School of Medicine in Nashville, Tennessee, and previously worked as a professor of neurology at Wake Forest University and the University of Michigan. Donofrio CV at 2–3. In addition to his teaching and research as a professor, he has a clinical practice as well that takes up half of his time, seeing thirty to forty patients per week with a wide variety of neurologic illnesses, including peripheral neuropathies, myasthenia gravis, and CFS. Tr. at 310, 311, 314. He acknowledged, however, that he only encounters CFS a handful of times per year. *Id.* at 339.

Dr. Donofrio began his testimony with a discussion of CFS. In his experience, CFS is reasonably considered as a possible explanation for generalized symptoms of weakness and fatigue that cannot otherwise be attributed to an identifiable neurologic or muscular problem. Tr. at 314. Dr. Donofrio disputed that CFS has an autoimmune basis, however, maintaining that (a) no autoantibody had ever been identified as associated with CFS, and (b) nothing was yet understood about the "passive physiology" of the condition's course (meaning how an autoantibody would interfere with some body process to cause CFS from a pathological perspective). *Id.* at 332–33.

In analyzing whether Petitioner's history suggested CFS as a proper diagnosis, Dr. Donofrio discussed and elaborated upon the same CDC criteria[27] reviewed by Dr. Fedele when she diagnosed Petitioner, adding that their application also required consideration of a patient's

[27] Dr. Donofrio also briefly addressed the proposed CFS criteria articulated by the Institute of Medicine (the "IOM"), which were released in 2015 and somewhat narrow the relevant criteria, focusing on two (post-exertional malaise and unrefreshing sleep) over other CFS factors listed in the CDC criteria, and adding additional symptoms to the list of relevant criteria. Tr. at 329–30 (discussing Ex. A Tab 1, filed July 27, 2015 (ECF No. 25-2)). Dr. Donofrio's testimony focused far more on the CDC criteria, and he opined that the IOM criteria are easier to meet, although he said he did not discount them altogether simply for that reason. *Id.* at 335.

medical history, a physical and mental health status exam, and lab tests. Tr. at 314–15. He emphasized that these criteria require a new onset of unexplained, persistent or relapsing fatigue that cannot be attributed to exertion, is not alleviated by rest, and which produces deficits in the patient's ability to engage in her life and occupation. *Id.* at 315 (discussing Ex. 125 at 1). He also underscored that included as an exclusionary criterion is evidence of "any past or current diagnosis of major depressive disorder." *Id.* at 316–17 (quoting Ex. 125 at 1).

Based upon the above, Dr. Donofrio reviewed Petitioner's medical record at hearing in an effort to demonstrate the basis for his opinion that she could not properly be diagnosed with CFS. He readily admitted that the records displayed many instances in which Petitioner reported debilitating fatigue. Tr. at 317. He questioned, however, whether any "impairment of memory" was evident in the medical record, especially since Petitioner was very proactive in seeking treatment and was otherwise never tested for mental deficits (procedures Dr. Donofrio deemed easy to perform) when her fatigue was evaluated by treaters. *Id.* at 317–19. He also noted a lack of evidence that Petitioner had a sore throat or swollen lymph nodes. *Id.* at 319. And he opined that there was a lack of medical record evidence that Petitioner was experiencing unrefreshing sleep. *Id.* at 323–24, 331. Dr. Donofrio distinguished this from mere fatigue or experiencing a "bad" sleep occasionally, adding that differentiating fatigue from persistent unrefreshing sleep would require careful treater inquiry. *Id.* at 324.

Dr. Donofrio took particular exception to the conclusion that Mrs. Yalacki demonstrated muscle pain, noting that there was ample pre-vaccination evidence of similar symptoms that also predated her 2011 claims of fatigue, reviewing medical records from as far back as 2008 and 2009 to support this contention. Tr. at 319–22 (discussing Ex. 1 at 56, 80, 125, 127). When asked on cross-examination about the relevance of evidence of symptoms so long before vaccination, he responded that the CDC criteria provide that such evidence bore on whether the aches or pain were in fact new, and thus would be proper to consider. *Id.* at 334–35 (discussing Ex. 125 at 1 (CDC criteria requires that muscle pain did *not* predate onset of fatigue in order to constitute a symptom of CFS)).

Dr. Donofrio also placed emphasis on one particular exclusionary criterion: the existence of a depressive disorder or other mental health condition. Tr. at 325.[28] Thus, he observed that

[28] After Respondent inquired of Dr. Donofrio's credentials and expertise, Petitioner's counsel objected to Dr. Donofrio being deemed or qualified as an expert on psychiatric matters, solely based on his neurologic training and background. Tr. at 312. I noted the reasonableness of the objection, and do not give great weight to testimony by Dr. Donofrio intending to offer a mental health diagnosis of Mrs. Yalacki. *Id.* at 312–13. However, because preexisting mental health issues bear on the appropriateness of a CFS diagnosis, and because Petitioner's record is replete with references to a variety of mental health problems, many of which predated vaccination, I give some consideration to such evidence, and whether (as a treater familiar with CFS) a practitioner like Dr. Donofrio would take such matters into account. *See id.* at 325 (Dr. Donofrio confirming a mental health diagnosis was not part of his opinion, even though he considered record evidence of Petitioner's reported mental health status in reaching his opinion as to the appropriateness of a CFS diagnosis).

records from before vaccination (and even the same month thereof) to more than one year after mentioned Petitioner's long-standing struggles with depression and anxiety. *Id.* at 325–26 (discussing Ex. 2 at 550 (November 2012 record)), 326–27 (discussing Ex. 1 at 327 (September 2010 record)), 327–28 (discussing Ex. 2 at 123–24 (June 30, 2011 record where treater "strongly recommended" depression treatment, which Petitioner refused)). He deemed the June 2011 record especially significant, as it reflected the fact that within a month of vaccination Petitioner was aware of the possibility that the actual source of her symptoms had nothing to do with the Hep B vaccine. *Id.* at 328–29.

The fact that Petitioner also experienced intermittent improvement, as reflected in her medical history, was further evidence to Dr. Donofrio that the CFS diagnosis was inaccurate. His read of the medical records suggested that Mrs. Yalacki was not experiencing fatigue or other such symptoms for approximately six months, from March until September 2012. Tr. at 331. In Dr. Donofrio's experience, it was unheard of for patients with CFS to experience "spontaneous six-month remissions." *Id.* at 331, 338. He did, however, admit that the severity of CFS symptoms could wax and wane from day to day, although an intercurrent infection (a URI, for example) might also make it mistakenly appear to an individual that her CFS had worsened. *Id.* at 332, 337–38.[29]

3. Dr. J. Lindsay Whitton

Dr. Whitton, an immunologist, was Respondent's third expert, offering two written reports in addition to his hearing testimony. *See* Ex. E, filed June 30, 2016 (ECF No. 38-1); Ex. M, filed Oct. 16, 2017 (ECF No. 64-1). He opined that Dr. Shoenfeld's view that the Hep B could cause CFS or POTS was scientifically unreliable. Tr. at 351.

As shown in his CV, Dr. Whitton received his medical degree, as well as a Ph.D. in molecular biology, from the University of Glasgow in Scotland. Ex. G at 1, filed June 30, 2016 (ECF No. 42-6) ("Whitton CV"). He currently works as a professor at Scripps Research Institute in La Jolla, California, where he both teaches and does research on the topics of virology and immunology. *Id.*; Tr. at 343–44. His research focuses on immunologic responses to viruses, making him very familiar with the innate and adaptive immune systems. Tr. at 347–48, 350. He serves on the editorial board of several reputable medical journals. Whitton CV at 1–2. Although not licensed as a medical doctor in the United States, Dr. Whitton maintained that the education and training he had received abroad was sufficient to meet those standards had he sought licensure. Tr. at 345–46.

[29] On cross examination, Dr. Donofrio allowed that such an intercurrent infection would constitute an "immune challenge," raising the possibility (to the extent that a person's existing CFS was worsened by the infection) that CFS itself is immune-mediated. Tr. at 335–36. However, Dr. Donofrio emphasized that the impact of such an infection would be felt by any person independent of their preexisting CFS. *Id.* at 336.

Dr. Whitton initially provided a series of definitions relevant to his opinion. He defined "antigen" as something (usually a protein) that triggers an adaptive immune response, whether in the form of the production of antibodies or a T cell response. Tr. at 353. Proteins are made up of chain of amino acids, of which there total twenty standard to the human body. *Id.* at 353–54. A chain of amino acids is called a peptide, and molecular mimicry can occur when a peptide in an antigenic protein shares "homology," or identity, with a self protein in the body, making both look the same to any immune response (antibodies or T cells) generated in reaction to the antigen. *Id.* at 355. Autoimmune disease will occur if that immune response mistakenly attacks the self protein or structure. *Id.* Dr. Whitton added that the term "molecular mimicry" applies only cases actually resulting in disease, and cautioned that it is incorrect to assume that homology between antigen components and a self protein will invariably result in harm. *Id.*

With the above as backdrop, Dr. Whitton turned to Petitioner's invocation of molecular mimicry as a mechanism by which the Hep B vaccine could cause an autoimmune response of *some* kind resulting in disease. He characterized Dr. Shoenfeld's argument as holding that a surface antigen of the vaccine included an amino acid peptide sequence that had homology with components of the norepinephrine transporter, and that the unusual nature of this homology resulted in a cross-attack by antibodies produced in response to the vaccine and causing autonomic dysfunction sufficient to result in CFS or POTS. Tr. at 352. He noted that Dr. Shoenfeld proposed a pentamer, or five amino acid chain sequence, was sufficient for homology to exist—but in Dr. Whitton's view, homology on that scale was wide-spread in the human body, and thus not rare at all. *Id.* at 356–58.

In support of this view, he referenced literature confirming that homology was "commonplace," and the reasonable result of the fact that human proteins were comprised of a finite set of amino acids. Tr. at 362–64 (discussing A. Silvanovich, et al., *The Value of Short Amino Acid Sequence Matches for Prediction of Protein Allergenicity*, 90 Toxicological Sciences 252 (2006), filed as Ex. E Tab 5, June 30, 2016 (ECF No. 38-6)). In fact, Dr. Whitton noted, if a mere match between a five-amino acid peptide component of an antigen and a self protein component were enough to result in molecular mimicry, "we would be dead" from all the autoimmune cross-reactivity that would result. *Id.* at 366, 377. Dr. Whitton therefore maintained that the homologous sequences identified by Dr. Shoenfeld were "cherry picked for this case," and amounted to selection bias rather than verified and reliable scientific evidence of a pathologic cross-reaction spurred by molecular mimicry. *Id.* at 361.

Dr. Whitton next attacked the bases for Petitioner's argument that the norepinephrine transporter is the target antigen for the alleged autoimmune cross-reactive process. Tr. at 366–67. He opined that Petitioner's normal plasma norepinephrine test result from 2013 reflected that she does not have a defect in that protein. *Id.* at 367. Further, with regard to Petitioner's argument

about homology between the Hep B vaccine and a specific target antigen, Dr. Whitton argued that Petitioner had mistakenly referenced homologous epitopes from the Hep C rather than Hep B virus, and that those that were derived from the Hep B virus were actually limited to a single homologous epitope. *Id.* at 371–72. And he proposed that the homologous self-epitopes in question are not "antibody epitopes" that would (mistakenly) recognize antibodies produced in response to the vaccine, but T cell epitopes, meaning that they were inconsistent with Dr. Shoenfeld's entire theory. *Id.* at 373.

Dr. Whitton also spoke to the purported timeframe in which Petitioner alleges to have experienced a vaccine reaction. Although he allowed that certain severe and immediate reactions by the adaptive immune system to vaccination are possible in a short timeframe (for example, anaphylaxis), he disputed that the record in this case revealed such a clear reaction. Tr. at 378. He more definitively rejected the notion that Petitioner's onset occurred within two hours of vaccination, noting that even Dr. Shoenfeld allowed for the fact that post-vaccine "malaise" might last for up to twenty-four hours. *Id.* at 379. In his understanding, the best models for how molecular mimicry leads to autoimmune cross-reactions have shown that it can take six to ten days for the antibody upregulation to occur, far longer than the short timeframes argued for by Petitioner. *Id.* at 379–81. He added that he would also expect some evidence of nonspecific indicators of an autoimmune process (such as proof of ongoing inflammation) to exist if Petitioner's timeframe for onset were accurate, although he admitted that such speculation on his part went beyond his expertise in this case as an immunologist and virologist. *Id.* at 390.

In addition to offering an opinion specific to components of Petitioner's causation theory, Dr. Whitton commented on the persuasiveness of that theory in light of the evidence offered in its support. He maintained that Petitioner had not offered broadly reliable evidence associating the Hep B vaccine with POTS or CFS. Tr. at 382. When challenged by Petitioner to enumerate what such evidence would look like, Dr. Whitton responded that he would need to see proof of (a) the relevant autoantibody, (b) evidence of Mrs. Yalacki's norepinephrine transporter protein dysfunction, or (c) some kind of experimental study or model establishing that the Hep B vaccine had been associated with the injuries alleged. *Id.* at 383–85. He also attacked Dr. Shoenfeld's questioning the possibility that an unidentified wild virus could have caused Petitioner's POTS or CFS, noting that in his view a viral infection was generally *more* likely to trigger disease or an aberrant immune response than a vaccine. *Id.* at 387–89.

III. Procedural History

As noted above, this case was initiated in April 2014. Petitioner subsequently filed relevant medical records, concluding the process on August 6, 2014, with the Statement of Completion

(ECF No. 13). Respondent's Rule 4(c) Report was thereafter filed on October 6th (ECF No. 14), in which Respondent challenged the appropriateness of an entitlement award.

Petitioner filed Dr. Shoenfeld's first expert report on December 22, 2015. Noting that Dr. Shoenfeld relied on his ASIA theory to explain vaccine causation in her case, I stated during a status conference that other special masters have repeatedly found this theory to be unpersuasive and scientifically unreliable. *See* Order, dated Jan. 5, 2016 (ECF No. 30).[30] After Petitioner filed an additional report from Dr. Shoenfeld that largely reiterated his prior statements invoking ASIA, I again expressed my concerns to Petitioner that reliance on this theory would be inadvisable. *See* Order, dated July 19, 2016 (ECF No. 47).

Petitioner subsequently filed additional expert reports from Dr. Shoenfeld that did not raise ASIA and supporting medical literature, as well as a written evaluation from Jack Kleid, M.D.[31] Respondent filed reports and literature from Drs. Low, Donofrio, and Whitton. Petitioner amended her claim on August 31, 2017, the same day she filed her prehearing brief, arguing in the alternative in both documents that the Hep B vaccine significantly aggravated a preexisting condition. *See* Am. Pet. at 2, filed Aug. 31, 2017 (ECF No. 56); Pet'r's Pre-Hr'g Br. at 7–14, filed Aug. 31, 2017 (ECF No. 58). Respondent submitted his prehearing brief in October of 2017, and a two-day entitlement hearing took place on January 22–23, 2018. The parties submitted post-hearing briefs on August 20, 2018. This case is now ripe for decision.

IV. Applicable Legal Standards

A. *Claimant's 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 and also occurring within a statutorily-prescribed period of

[30] In my Order, I directed Petitioner's attention to the following Vaccine Program cases in which special masters did not accept the ASIA theory as a scientifically-reliable explanation for vaccine-caused injuries: *Rowan v. Sec'y of Health & Human Servs.*, No. 10-272V, 2014 WL 7465661 (Fed. Cl. Spec. Mstr. Dec. 8, 2014), *mot. for review denied*, 2015 WL 3562409 (Fed. Cl. June 9, 2015); *D'Angiolini v. Sec'y of Health & Human Servs.*, No. 99-578V, 2014 WL 1678145 (Fed. Cl. Spec. Mstr. Mar. 27, 2014), *mot. for review denied*, 122 Fed. Cl. 86 (2015).

[31] Although Dr. Kleid's CV was not filed in this case, his report indicates that he works as an associate professor of cardiology at the University of California San Diego. Ex. 115 at 15, filed Nov. 17, 2016 (ECF No. 50-1). Dr. Kleid's report contains a review of Mrs. Yalacki's medical record, as well as a discussion of his evaluation of her. *See generally id.* He conducted a form of video surveillance over three- and six-day periods in February, April, and September of 2016. *Id.* at 2, 12. He proposed other diagnostic tests, including a treadmill stress test, which Petitioner declined to undergo. *Id.* at 12. Based on his review of the records and the video surveillance of Mrs. Yalacki, Dr. Kleid concluded that she suffers from POTS and CFS. *Id.* at 13. However, because his opinion bears only on her 2016 condition—five years after the vaccination at issue—and because he was not called to testify, I give his written opinion very little weight.

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; *see also Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995) (quoting 42 U.S.C. § 11(c)(1)(C)(i)); *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).[32] Petitioner in this case asserts only a non-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). 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).

When a Table Injury claim is successfully established, causation is presumed. 42 C.F.R. § 100.3. Table claims must satisfy with evidence the specific elements of the relevant claim, including the definitions of terms set in the Qualifications and Aids to Interpretation (the "QAI"). Section 14(b). Case law underscores that, to obtain the benefit of the presumption of causation associated with a Table claim, the claim's requirements must be strictly construed. *Miller v. Sec'y of Health & Human Servs.*, No. 02-235V, 2015 WL 5456093, at *24 (Fed. Cl. Spec. Mstr. Aug. 18, 2015) (requiring petitioner to satisfy the "strict Table definition" of encephalopathy).

For a non-Table claim, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In such circumstances, 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 asserting a non-Table claim must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health & Human Services*: "(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." 418 F.3d 1274, 1278 (Fed. Cir. 2005).

[32] 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).

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, the 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), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biologic plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States*, 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first Althen prong by preponderance; that standard applied only to second prong and petitioner's overall burden); *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)); *see also Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the preponderance standard applied when evaluating a claimant's overall success in a Vaccine Act claim also bears on the first *Althen* prong. *See, e.g.*, *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant vaccine to relevant injury]") (emphasis added). Regardless, one thing remains: petitioners always have the burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance).

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).

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 Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. 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." *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. denied 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 denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & 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 a 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"); *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 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

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*, 968 F.2d 1226 (Fed. Cir.), *cert. denied sub nom. 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 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 over contrary testimony, 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 Pharmaceuticals, 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 fora (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*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

D. *Consideration of Medical Literature*

Both parties relied on significant amounts of medical and scientific literature to support their respective positions. I have reviewed all of the medical literature submitted in this case, although my decision does not discuss each filed article in detail (nor would it be reasonable to require a special master to do so—especially in a case like this, where far more literature than was

necessary has been filed).[33] *Moriarty v. Sec'y of Health & Human Servs.,* 844 F.3d 1322, 1328 (Fed. Cir. 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).

ANALYSIS

I. Overview of Medical Terms and Relevant Prior Decisions

A. *POTS*

The experts testifying at hearing defined POTS correctly for the most part, although a few additional points should be made about it. POTS is unquestionably a *subset* of orthostatic intolerance, not a wholly separate clinical entity. *See* R. Freeman, et al., *Consensus Statement on the Definition of Orthostatic Hypotension, Neurally Mediated Syncope and the Postural Tachycardia Syndrome*, 21 Clinical Autonomic Res. 69, 69 (2011), filed as Ex. A Tab 4, July 27, 2015 (ECF No. 25-5) ("Freeman"). It is marked by an increase in heart rate, or tachycardia, caused by a change in body position from the supine position to the upright position, without an accompanying increase in blood pressure. *See* Freeman at 71; B. Grubb, et al., *The Postural Tachycardia Syndrome: A Concise Guide to Diagnosis and Management*, 17 J. Cardiovascular Electrophysiology 1, 1 (2006), filed as Ex. 35, Mar. 31, 2016 (ECF No. 34); P. Low, et al., *Postural Tachycardia Syndrome (POTS)*, 20 J. Cardiovascular Electrophysiology 352, 352–53 (2008), filed as Ex. 59, Mar. 31, 2016 (ECF No. 34) ("Low").

In POTS, an individual's inability to make a "prompt physiological adaptation to gravity" results in feelings of dizziness and lightheadedness, as well as fatigue, headache, and exercise intolerance. S. Raj, *The Postural Tachycardia Syndrome (POTS): Pathophysiology, Diagnosis & Management*, 6 Indian Pacing & Electrophysiology J. 84, 84 (2006), filed as Ex. 39, Mar. 31, 2016 (ECF No. 34) ("Raj"). Thus, a claimant alleging a vaccine injury of POTS is arguing that the relevant vaccine has done *something* to the autonomic system sufficient to cause a chronic aberrant response to orthostatic change.

There are several POTS variants with different possible etiologies, although research has not conclusively established any one particular explanation for most POTS cases. Freeman at 72.

[33] This case unquestionably stands as an example of the over-filing of literature by a petitioner. By my informal account, Petitioner filed *more than one hundred* articles in support of her claim. Although admittedly a large number of them involve the abandoned ASIA theory, this still seems excessive, especially in light of the fact that both experts only directly addressed a fraction of these articles in their hearing testimony. Indeed, Petitioner filed so many individual articles in the course of supplementing Dr. Shoenfeld's opinions that she ended up mistakenly *refiling* the same articles several times over. *See, e.g.*, Exs. 35 and 72 (same article), Exs. 37 and 69 (same article), Exs. 47 and 62 (same article), and Exs. 67 and 99 (former an abstract of the latter).

Two proposed etiologies for POTS are a hyperadrenergic state (meaning elevated norepinephrine concentrations) leading to tachycardia, or a neuropathic variant resulting from autonomic nerve fiber damage. Thieben at 308, 313; Freeman at 72; *see also* K. Kimpinski, et al., *A Prospective, 1-Year Follow-up Study of Postural Tachycardia Syndrome*, 87 Mayo Clinic Proc. 746, 746 (2012), filed as Ex. 37, Mar. 31, 2016 (ECF No. 34) ("Kimpinski"). But POTS can also be the secondary result of other conditions—lower limb blood pooling, hypovolemia (meaning decreased blood plasma), or deconditioning due to inactivity (as Dr. Low explained). Kimpinski at 746; Thieben at 308. POTS is more commonly experienced by women. Freeman at 72; Raj at 86.

There is reliable literature exploring the possibility (as emphasized by Petitioner) that *some* cases of POTS could be autoimmune-mediated. *See, e.g.*, Thieben at 311, 313 (noting that six of forty-two patients tested positive for a particular ganglionic antibody); X. Wang, et al., *Autoimmunoreactive IgGs Against Cardiac Lipid Raft-Associated Proteins in Patients with POTS*, 162 Translational Res. 1, 34, 34–35 (2013), filed as Ex. 99, Mar. 31, 2016 (ECF No. 34) (study finding presence of autoantibodies against cardiac membranes in POTS patients; Dr. Low as co-author). The neuropathic form of POTS in particular was previously speculated to be autoimmune in origin. Low at 354. However, at hearing Dr. Low testified that after studying the matter for some time, he personally had moved away from autoimmunity as the most likely explanation for POTS in the majority of individuals, and even Thieben allows that autoimmune-implicated POTS would *not* be the most common way in which it occurs—and if it did, would be accompanied by evidence of "sympathetic denervation." Thieben at 312–13; Low at 354 (noting that neuropathic POTS is evidenced by axon reflex tests or sweat tests that reveal "sudomotor denervation to the foot and toes").[34] At a minimum, an individual suffering from an autonomic neuropathy mediated by autoimmunity would have a number of presenting symptoms, *in addition to* orthostatic tachycardia, revealing harm to the autonomic nervous system.

I have twice had the opportunity to consider whether certain forms of orthostatic intolerance can be vaccine-caused, albeit in the context of a different vaccine, the human papilloma virus ("HPV") vaccine. *See generally Johnson v. Sec'y of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760 (Fed. Cl. Spec. Mstr. Mar. 23, 2018); *Combs v. Sec'y of Health & Human Servs.*, No. 14-878V, 2018 WL 1581672 (Fed. Cl. Spec. Mstr. Feb. 15, 2018). In both cases, I found the petitioner had not met the burden of proof.

[34] In addition, Dr. Low in his own writing has moved away from finding significant the fact that some individuals with POTS reported experiencing a viral infection prior to their symptoms, further diminishing the likelihood that most cases of POTS would be autoimmune in nature (since viral infection would be in most cases the likely start for a pathogenic autoimmune cross-reaction). *Compare* Thieben at 310 (90.5% of studied patients had experienced an antecedent infection) *with* Low at 353 (noting that "recent experience" has suggested an antecedent infection is less common in POTS patients than previously proposed). Low was published only two years after Thieben, and both articles are now at least ten years old.

Johnson is more on point with the present case. There, a young woman alleged that the HPV vaccine caused POTS diagnosed several years after vaccination, relying (as here) on the testimony of Dr. Shoenfeld (whose initial intent to offer ASIA as an explanation was rejected by me in advance in that case as well, and for the same reasons). *Johnson*, 2018 WL 2051760, at *7 n.11, *26 n.35. In determining that the petitioner had not established a reliable medical causation theory, I found that she failed to demonstrate that POTS is generally autoimmune in origin. *Id.* at *24–25. I also determined that the petitioner's overall disease course, measured from the date of the alleged causal vaccination to the time her symptoms were thought to possibly reflect POTS, was simply too meandering and lengthy to deem it a medically reasonable timeframe. *Id.* at *22–25.

Combs, by contrast, only involved a claim that a young woman developed syncope well after receipt of the HPV vaccine. *Combs*, 2018 WL 1581672, at *1. But Respondent, as here, called upon Dr. Low, who provided extensive testimony about the autonomic nervous system and discussed the same kind of orthostatic intolerance issues raised in this case. After a hearing and full consideration of the evidence and expert testimony, I found that the petitioner had not established that her condition arose from damage to the autonomic nervous system (as there was no such evidence to support that contention), nor that her syncope was likely vaccine-caused. *Id.*

Such decisions do not dictate the outcome of this case. However, they do demonstrate the existing lack of persuasive scientific evidence associating vaccination to significant orthostatic intolerance (beyond recognized, close-in-time reactions like syncope, which is itself a Table claim for certain vaccines including Hep B (42 C.F.R. § 100.3 VIII(C) (2018)), as well as the kind of hurdles a petitioner faces in attempting to obtain an entitlement award based on such a theory. These hurdles bear especially on the present case, as discussed below.

B. *CFS*

The primary characteristic of CFS is "severe disabling fatigue," which is accompanied by other symptoms including memory and concentration impairment, muscle pain, and impaired sleep. *See* K. Fukuda, et al., *The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study*, 121 Annals of Internal Med. 953, 953 (1994), filed as Ex. Q, Oct. 16, 2017 (ECF No. 65-2). CFS is, to some extent, a diagnosis of exclusion, as a patient can only properly be diagnosed with it once other potential causes have been ruled out. *See id.* Many CFS patients also suffer from POTS, and the conditions are considered to overlap. R. Sheldon, et al., *2015 Heart Rhythm Society Expert Consensus Statement on the Diagnosis and Treatment of Postural Tachycardia Syndrome, Inappropriate Sinus Tachycardia, and Vasovagal Syndrome*, 12 Heart Rhythm e41, e43 (2015), filed as Ex. N Tab 2, Oct. 16, 2017 (ECF No. 64-8) ("Sheldon").

Petitioners alleging a CFS injury resulting from the Hep B vaccine have been successful in two reasoned Vaccine Program decisions,[35] but both are facially distinguishable because in each the petitioner's vaccine was demonstrated to have contributed to an *existing* documented disease process. In *Doe/68 v. Secretary of Health & Human Services*, No. [redacted], 2010 WL 2300592 (Fed. Cl. Spec. Mstr. May 24, 2010), the petitioner already suffered from chronic inflammation as a result of "decades of urinary tract and allergic conditions, and chronic leakage from silicone capsules [breast implants]" prior to receiving the Hep B vaccine. *Doe/68*, 2010 WL 2300592, at *35. The special master found that the Hep B vaccine was thus a substantial factor that combined with her preexisting and demonstrated chronic inflammation to cause chronic fatigue. *Id.* Similarly, in *Doe/52 v. Secretary of Health & Human Services*, No. [redacted], 2009 WL 2506199 (Fed. Cl. Spec. Mstr. Dec. 15, 2009), a petitioner alleged that the Hep B vaccine reactivated the latent Epstein-Barr virus she had contracted prior to vaccination, which also played a substantial factor in generation of her CFS. *Doe/52*, 2009 WL 2506199, at *14. Mrs. Yalacki, by contrast, alleges no such combination of factors or reactivation of a prior condition.

II. Petitioner Has Not Established Grounds for Entitlement Based on Her POTS Claim with Sufficient Preponderant Evidence

A. *Petitioner Has Not Established a Plausible Causation Theory*

Having heard the experts and reviewed each side's medical literature and reports, I find that Petitioner has not presented a plausible theory, supported by sufficient reliable evidence, that the Hep B vaccine can cause POTS.[36]

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[35] An unsuccessful Hep B/CFS petitioner's case was initially reversed by the Court of Federal Claims on appeal in *Dobrydnev v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 190 (2011). However, the Federal Circuit subsequently reinstated the special master's decision denying entitlement. 566 F. App'x 976 (Fed. Cir. 2014). In another case, a petitioner who fell ill after receiving his second Hep B shot claimed a wide variety of symptoms, including some characteristic of CFS. *Dunbar v. Sec'y of Health & Human Servs.*, No. 98-627V, 2007 WL 2844826, at *14, *18 (Fed. Cl. Spec. Mstr. Sept. 14, 2007). The special master ruled in the petitioner's favor, but did not expressly find that the petitioner had CFS. *See id.* at *27–28.

[36] In her Amended Petition and Prehearing Brief, Petitioner also alleged (in the alternative) that the Hep B vaccine significantly aggravated her preexisting POTS and/or CFS. Am. Pet. at 2; Pet'r's Pre-Hr'g Br. at 7–14. Petitioner briefly reiterated this argument in her Post-Hearing Brief as well. *See* Pet'r's Post-Hr'g Br. at 12 n.1. She did not, however, attempt to substantiate this claim with expert testimony at hearing, focusing instead on her post-vaccination symptoms, and with Dr. Shoenfeld only addressing the capacity for the vaccine to cause directly either alleged injury—not make the conditions qualitatively worse.

Regardless, even if Petitioner had more robustly sought to defend her halfheartedly-alleged significant aggravation claim, such a claim could not be preponderantly established on this record. Among other things, a significant aggravation claim must establish a *worsening* of a petitioner's condition beyond what would be expected absent vaccination, which is not apparent here. *Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 137 (2009). The record does not establish that the vaccine caused an immediate reaction (despite Petitioner's claims to the contrary), and treater evaluations in fact did *not* support CFS or POTS in the first two months after vaccination—precisely when worsening should have been evident. Her overall course also does not seem to follow a trajectory of worsening (and indeed her CFS symptoms even abated for a period in 2012). In addition, as *Loving* recognizes, a significant aggravation claim must meet all of the underlying *Althen* prongs—but as set forth in §§II(A–B) and §III(A) of this

Before discussing specific deficiencies in Petitioner's theory, it is appropriate at the outset to note the competence and qualifications gap separating both sides' experts.[37] Respondent offered two experts (putting aside Dr. Donofrio, who focused on CFS), one of whom happens to be one of the foremost authorities on the autonomic nervous system—in the United States if not the world. Petitioner, by contrast, utilized a single causation expert, Dr. Shoenfeld, who has previously testified unpersuasively before me on the same topic, and whose expertise on the immune system and autoimmunity in general was not accompanied by comparable expertise in treating or studying POTS and CFS (beyond addressing it as another possible autoimmune disease likely explained by his ASIA theory). *See Johnson*, 2018 WL 2051760, at *7–12, *23.

Dr. Shoenfeld's deficiencies as an expert in this case go beyond his comparative lack of competence on POTS or the autonomic nervous system, however. For time and again, when testifying in Vaccine Program cases, Dr. Shoenfeld has readily voiced his belief about the prevalence of autoimmunity and its unerring connection to vaccination—a view so deeply entrenched and unshakable that it often defies the very legal standards I am called to apply (especially when he is asked about the timeframe over which such autoimmunity might germinate). *See, e.g.*, *Garner v. Sec'y of Health & Human Servs.*, No. 15–063V, 2017 WL 1713184, at *16–17 (Fed. Cl. Spec. Mstr. Mar. 24, 2017), *mot. for review denied*, 133 Fed. Cl. 140 (2017); *Crutchfield v. Sec'y of Health & Human Servs.*, No. 09-0039V, 2014 WL 1665227, at *11–13 (Fed. Cl. Spec. Mstr. Apr. 7, 2014); *Hennessey v. Sec'y of Health & Human Servs.*, 91 Fed. Cl. 126, 142 (2010) (rejecting Dr. Shoenfeld's attempt to satisfy the third *Althen* prong by positing that any timeframe is appropriate). Such blanket assertions harm his overall credibility.

Dr. Shoenfeld was generally qualified to give an opinion in this case, and I have considered that opinion carefully. But he is comparatively lacking in expertise with the autonomic nervous system or POTS, and that, in addition to his other demonstrated biases and deficiencies (not to mention the apparent misrepresentations on his CV pointed out at hearing by Respondent),[38] leads me to give less weight overall to his pronouncements about POTS and its causes than to the testimony of Respondent's experts, who together provided a comprehensive and more persuasive picture of the condition at issue and the low likelihood that a vaccine could instigate it.[39]

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decision, Petitioner has not carried her preponderant burden of proof on direct causation, a failure that undermines a significant aggravation claim a well.

[37] I do not include the treating physicians who testified on Petitioner's behalf in this calculation, since they did not offer opinions on causation.

[38] *See supra* note 18.

[39] Of course, a different presentation by Petitioner (if supported by experts who matched Respondent's experts' qualifications to opine on the autonomic nervous system or vaccine interaction with the same) might lead to a different outcome. But it is within my discretion to evaluate expert credibility (a function of the expert's competence to testify

But even if I had found Dr. Shoenfeld more credible or persuasive as an expert, I would still find significant deficiencies in Petitioner's causation theory with respect to POTS. Petitioner proposed that POTS is usually an autoimmune disease, mediated by autoantibodies produced in response to the Hep B vaccine that cross-react with norepinephrine transporter proteins, interfering with the autonomic nervous system to cause orthostatic imbalance. But Respondent effectively rebutted that assumption. Admittedly, there is literature support (such as Thieben) for the idea that a *particular form* of autonomic neuropathy might be associated with a particular autoantibody, thereby suggesting autoimmunity as the pathologic mechanism. But Dr. Low (whose direct experience studying the etiology of POTS far outweighed Dr. Shoenfeld's) persuasively established that an autoimmune explanation for POTS is far less accepted today than when first written about in Thieben (an article *he co-authored*) ten years ago; he does not test for the presence of autoantibodies in POTS patients in most cases, and POTS is not treated with immune system suppression methods like plasmapheresis. The remaining scientific evidence offered by Petitioner suggesting the POTS is typically autoimmune was thin, relying on single case reports (Shannon), a kind of evidence not given significant weight in Program cases,[40] or only indirectly supported a connection between autoimmunity and conditions such as POTS (*see, e.g.*, Li). And Dr. Shoenfeld in no way undercut Dr. Low's testimony (corroborated by several items of literature) that there are other POTS variants that clearly are *not* autoimmune in etiology, such as hyperadrenergic POTS or POTS due to deconditioning, or that these are more common explanations for the condition. *See* Low at 354–56.

Next, even if it is granted that some rare forms of POTS *are* autoimmune in origin, there remain substantial deficiencies in Petitioner's theory that the Hep B vaccine could trigger a pathogenic process resulting in such an autoimmune attack leading to POTS. As I have noted before, it is not enough for a claimant to invoke the concept of molecular mimicry along with *some* identified homology between an amino acid sequence and a target antigen in order to carry her burden. *Johnson*, 2018 WL 2051760, at *26. Rather, a petitioner needs to cite to evidence, circumstantial or otherwise, suggesting reason to find it plausible that the proposed autoimmune cross-reaction triggered by the relevant vaccine *does occur*. But Petitioner offered nothing reliable to support the contentions that (a) the Hep B vaccine likely does cause the production of antibodies associated with autonomic damage or interference sufficient to cause POTS (as opposed to different diseases known to be predominantly autoimmune), and (b) that those same antibodies do lead to such a pathogenic process.

Such points were also effectively undermined by Dr. Whitton's testimony on immunologic topics relevant to *Althen* prong one. Dr. Whitton was broadly persuasive in his points about the

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on a topic, but also a matter that is impacted by a given expert's honesty, clarity, and overall persuasiveness) in determining if a petitioner has carried her burden of proof. *See Broekelschen*, 618 F.3d at 1347.

[40] *See, e.g., Crutchfield*, 2014 WL 1665227, at *19.

limited conclusions that one could draw from evidence of amino acid sequence homology (especially where, as here, it appears to have been cherry-picked to bulwark a theory, rather than discovered in studying POTS and its pathogenesis). He similarly established convincingly that the evidence that the norepinephrine transporter protein is the target antigen for autonomic nervous system interference sufficient to result in POTS is undeveloped, as is the front-end component of Petitioner's theory proposing that some specific components of the Hep B vaccine *can* mimic a target antigen epitope on the transporter protein that would be the subject of an autoimmune attack.

Because Petitioner could not point to any studies linking the Hep B vaccine to POTS or autonomic neuropathy of any kind,[41] she had to rely on the little existing circumstantial evidence that suggests it *could* be autoimmune, and theorize how that process might work, or the association of the Hep B vaccine with other, distinguishable autoimmune diseases. But the evidence she offered connecting the Hep B vaccine to POTS was speculative, limited, or rebutted, and she could not breathe life into it with Dr. Shoenfeld's *ipse dixit* pronouncements on topics about which he knew demonstrably less than Dr. Low. Petitioner has therefore not established a plausible causation theory connecting the Hep B vaccine to POTS.

B. *Even if Petitioner Had POTS, the Record Does Not Establish That It Was Caused by the Hepatitis B Vaccine*

The record is not in agreement as to whether Mrs. Yalacki actually ever had (or today has) POTS. There are ample points in the medical record where Petitioner demonstrated clinical indicia of POTS, such as dizziness and fatigue. But she experienced such symptoms both before *and* after the vaccination at issue, making it difficult to give more significance to her symptoms in the summer of 2011 than to her pre-vaccination history and the many congruent complaints recorded therein.[42]

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[41] My observation that Petitioner has not *offered* direct evidence associating the Hep B vaccine with POTS is not equivalent to *requiring* such evidence. As I have already noted above in my discussion of the legal standards applicable to Program cases, there is no particular category of evidence a petitioner must file to prevail on her claim, and claimants can unquestionably offer reliable circumstantial proof to support their theory (and do so successfully all the time). To give but one possible example, a petitioner is not required to offer epidemiologic evidence establishing the incidence of injury X after receipt of vaccine Y—and so the fact that a petitioner cannot cite an epidemiologic study establishing such an association is not grounds for a claim's summary dismissal (in the same way it would be, by comparison, if a petitioner could not prove the fact of vaccination). But (as the Federal Circuit recently reiterated) consideration by a special master of epidemiologic evidence that *exists* and that is *unhelpful* to a petitioner's claim is not tantamount to *requiring* that such evidence be submitted. *D'Tiole v. Sec'y of Health & Human Servs.*, 726 F. App'x 809, 811–12 (Fed. Cir. 2018). Thus, as part of the evidentiary weighing process, I may take into account the nature of the evidence offered, and doing so does not mean I am elevating Petitioner's burden.

[42] Because POTS is understood to be difficult to diagnose, symptoms can long precede a formal treater determination designating POTS as the best descriptor for a patient's symptoms. *See* Sheldon at e44. This means that, just as a symptom in 2011 could be related to a POTS diagnosis Ms Yalacki received in 2012 or 2013, symptoms she experienced *before* the vaccination could equally be associated with such later diagnoses.

Treater support for the diagnosis is also inconclusive. Some treaters (Drs. Gillespie and Betkowski, for example) seem to have either leaned in favor of a POTS diagnosis or outright proposed it, although they based their determinations on a sit-stand test or Petitioner's own recitation of her medical history as having been diagnosed with POTS in the past, without corroborating the diagnosis with follow-up testing, and recommended further testing as well to confirm the diagnosis's accuracy. Dr. Gillespie was certainly a credible witness, giving his diagnosis some heft, but it is self-evident that his testimony was based solely on two encounters with Petitioner that occurred almost three years after her receipt of the Hep B vaccine. And as Dr. Low explained, some of the sit-stand orthostatic readings upon which these treaters relied were less supportive of the diagnosis than they believed. *E.g.*, Ex. 2 at 667, 702 (Petitioner's blood pressure *dropped* during March 2013 and April 2013 sit-stand tests with Dr. Betkowski, which would be inconsistent with POTS diagnosis); Ex. 12 at 34 (Dr. Gillespie finding a sit-stand test result of heart rate increase from seventy-one BPM to eighty-eight BPM to support a POTS diagnosis despite diagnostic criteria of thirty BPM increase or greater).

On the other hand, an equal number of treaters ruled out POTS or doubted its diagnostic veracity—and they did so on the basis of better testing evidence. Dr. Abruzzo, for example, appears to be the first cardiologist Petitioner saw in 2011 who hypothesized her symptoms could be the product of autonomic neuropathy, but he also is the *only* treater to have performed a tilt table test, and the results of that test did not confirm POTS, causing him to abandon his initial speculation as to the source of her symptoms. Ex 5 at 84. Another cardiologist, Dr. Noll, acknowledged the contrary diagnostic evidence unsupportive of the diagnosis. And two other treaters (neurologists Drs. Rollins and Seibert) did not accept the diagnosis at all. Furthermore, I find that the tilt table test is in fact the accepted best clinical test for POTS, and reject Dr. Shoenfeld's conclusory assertions embracing the sit-stand test over it as wholly unpersuasive. The result of the single tilt table test Petitioner received—as well as the fact that she has never had a follow-up test—makes it extremely difficult to accept the POTS diagnosis given the overall inconclusiveness of this record.

However, even if I assume (consistent with the remedial nature of the Vaccine Program, and the concurrent admonition that special masters decide close issues in a petitioner's favor (*Capizzano*, 1440 F.3d at 1327)) that Petitioner *did* have POTS, the record strongly contradicts Petitioner's argument that it could have been caused by her June 2011 Hep B vaccine.

Fundamentally, the record does not reflect the causation theory proposed by Dr. Shoenfeld as having occurred in "real time." Petitioner posits that the Hep B vaccine initiated an autoimmune reaction mediated by autoantibodies that would have been produced not long after the June 2, 2011 vaccination. But there is no evidence the Petitioner even *had* these antibodies, and no evidence that she was experiencing an autoimmune process at all. This could be corroborated, for example, by lab tests suggesting the presence of inflammation, or contemporaneous treater speculation about

the character of her symptoms—and yet the work-ups Petitioner received in the summer of 2011 did *not* so find. In addition, Petitioner's theory proposes the autoantibodies interfering with the norepinephrine transporter protein—but there is no corroborative evidence of *other* symptoms that this transporter was malfunctioning (beyond the fact of the POTS symptoms themselves) – and as Dr. Low observed, later testing of her norepinephrine levels did not reveal any concerns.[43]

Dr. Low otherwise persuasively established that the kind of autoimmune neuropathy he once postulated as conceivable (but today doubts as explanatory for the vast majority of POTS cases) would be characterized by a host of *concurrent* symptoms reflective of autonomic nervous system harm—none of which have been shown to be present in this case. *See* Tr. at 272–74. Petitioner cannot show that she has any of the symptoms or test results that would be associated with an autonomic neuropathy (for example, loss of bladder control). And no treater has (based on identifiable testing or other evidence) causally connected Petitioner's POTS to her vaccination, while there is record evidence from close in time to the vaccination (specifically Petitioner's consultations with Drs. Jarrell and Mogyoros) that rebuts any assertion of a vaccine relationship, and which is based on actual testing rather than Dr. Shoenfeld's suppositions. Ex. 2 at 23, 68.

In addition, the record suggests credible alternative explanations for Petitioner's POTS symptoms that Petitioner did not persuasively rebut (or even address).[44] As noted, Petitioner's medical history is rife with evidence, both pre- and post-vaccination, that she struggled with mental health problems, and her numerous, repeated visits to medical treaters strongly suggest that anxiety about her health drove these visits. Some early treaters like Drs. Jarrell and Burton in 2011 went so far as to explicitly propose a relationship between Petitioner's overall symptoms and her mental health. Ex. 2 at 123–24, 155–56. In addition, Dr. Low posited that some of Petitioner's symptoms could be attributable merely to deconditioning associated with inactivity—a theory more consistent with the record than Dr. Shoenfeld's proposed autoimmunity theory. And the instances

[43] The fact that such testing was performed long after vaccination bears somewhat on the weight I give it—but the same is true for the testing results from 2013 and after that Petitioner argues support her POTS diagnosis, all of which *also* come more than a year after vaccination.

[44] In discussing these alternative explanations for Petitioner's symptoms, I am not engaging in a formal "alternative cause" or "factor unrelated" analysis. *See Flores v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 157, 162 (2014) (citing Section 13(a)(1)(B)); *Hazelhurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306, at *18 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010). That analysis would occur only if I had determined that Petitioner had carried her initial burden of proof, shifting the burden to Respondent. *Flores*, 115 Fed. Cl. at 162; *Hazelhurst*, 2009 WL 332306, at *18. Rather, I am noting that the record contains numerous facts unhelpful to Petitioner on the *Althen* "did cause" prong that impacted her success in establishing it by a preponderance, and that she failed to rebut or minimize the importance of these facts. It is unquestionable that as a matter of law I may consider such evidence when analyzing Petitioner's success in meeting the *Althen* prongs. *Bazan*, 539 F.3d at 1353 ("[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief").

of fatigue or dizziness reported by Petitioner prior to vaccination could also be related to her post-vaccination symptoms.

All in all, the record does not support the conclusion that the Hep B vaccine had anything to do with Mrs. Yalacki's POTS—and in fact, I cannot conclude on the basis of this record, or on Dr. Shoenfeld's conclusory testimony, that she has POTS at all (although there is evidence from long after the vaccination that supports that conclusion). Rather, and at best, the record suggests (consistent with Dr. Low's testimony) that Mrs. Yalacki has suffered from a mild form of orthostatic intolerance, the etiology of which has not been determined.

C. *Petitioner Has Not Demonstrated that Her POTS Began in a Medically-Acceptable Timeframe After the June 2, 2011 Vaccination*

Petitioner's claim also fails on her inability to establish that her POTS (assuming it exists, and assuming it *could* be vaccine-caused) began in a medically-acceptable timeframe in relation to her June 2011 vaccination.

Establishing onset of Petitioner's POTS in this case is difficult. Because POTS can be difficult to diagnose (and given that onset is a function of the initial symptom rather than date of diagnosis, under applicable Vaccine Program law), Petitioner can point to virtually any evidence in the medical record of a symptom that could suggest dizziness or fatigue and deem it the first symptom relating to a subsequent POTS diagnosis. Thus, although the best *diagnostic* proof of Petitioner's POTS comes from 2013 and 2014, when Petitioner saw Drs. Betkowski and Gillespie, those diagnoses—made years after the June 2011 vaccination—do not necessarily establish when her POTS may have *begun*.

Here (and in the same way the record is inconsistent as to whether Petitioner had POTS at all), there are many instances post-vaccination that could be deemed the onset of her POTS. Although the record reflects Petitioner's belief that her vaccine reaction began within hours after she received the Hep B vaccine, Dr. Shoenfeld seemed to argue for an onset later in the month of June. *See* Tr. at 191. I find, however, that the onset did not likely occur in 2011 *at all* (and thus too long after vaccination to be medically reasonable), and that regardless of when it did occur, Petitioner has not even established what a reasonable timeframe would be for autoimmune-associated POTS.

First, the medical record is not supportive of Petitioner's contention about onset close in time to vaccination. The only treater in 2011 who considered POTS (or any other kind of harm to or interference with the autonomic nervous system) to be a viable explanation for Petitioner's reported symptoms was Dr. Abruzzo—but his testing (which included a tilt table test) did not confirm the supposition, thus allowing for the inference that earlier symptoms were not initial

manifestations of the condition either. And as noted above, several treaters who saw Petitioner immediately around the time of vaccination disputed her belief that her symptoms were vaccine-related, at least as of that time. Accordingly, the record does not support the conclusion that Petitioner's POTS began before Dr. Abruzzo saw her in September 2011—three months post-vaccination.

As late as 2013, treaters like Dr. Rollins still doubted Petitioner had POTS—although around the same time Dr. Betkowski determined the contrary (albeit based on the less precise sit-stand test). It was only thereafter that sit-stand tests suggested to treaters like Dr. Gillespie that Petitioner might have POTS—although his recommendation that she see a specialist like Dr. Noll did not fully confirm the diagnosis.

Such a record does not allow for the conclusion that Petitioner's POTS symptoms began in late June 2011. In fact, it is almost impossible for identify *what* the onset would be, given the ample evidence of orthostatic intolerance *before* vaccination. *See, e.g.*, Ex. 1 at 9–13, 70, 482–83. Dr. Shoenfeld seemed to concede this, but posited in response that the mere fact onset occurred post-vaccination was proof of a relationship—a contention irreconcilable with Vaccine Program precedent. Tr. at 191 ("[t]he start might have been immediately after the vaccine, the start might have been several days after the vaccine, the start might have been also several weeks after the vaccine . . . we cannot know"); *McCarren v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 142, 147 (1997). It is therefore impossible to say if the timeframe from vaccination to onset is reasonable, as no onset can be identified.

This leads to the second significant problem with Petitioner's establishment of the third *Althen* prong. Petitioner has not credibly set forth, with persuasive expert testimony supported by reliable scientific evidence, what the reasonable timeframe *would be* in which POTS caused by a vaccine-induced autoimmune process would likely occur. Dr. Shoenfeld seems to believe that almost *any* post-vaccination time period is medically reasonable: "[t]he autoimmune effects can appear late (after the first vaccine) and can appear earlier even 90 minutes (after the second or third vaccine) due to the **boost reaction** ! especially in hyper reactive subjects (like HLA-DRB1). It is individual and genetically determined." Shoenfeld Second Rep. at 3 (emphasis in original). But such contentions were not bulwarked with reliable literature establishing either that POTS could take a meandering, smoldering course over many years, or (more importantly) that the alleged autoimmune process resulting in autonomic neuropathy would take more than six months, or even a year, before manifesting as POTS sufficient to receive the diagnosis.

Petitioner's onset arguments thus left too many loose ends relating to the reasonableness of the timeframe. If Petitioner were correct, and her orthostatic intolerance symptoms began as early as July 2011, how was it that the autoimmune process continued for a longer time, such that her symptoms progressed for nearly two years before those symptoms were overt enough for a

treater to recognize that she had POTS? And why did she not test positive for POTS when evaluated in 2011 by Dr. Abruzzo? Or if closer in time to the diagnosis by Drs. Betkowski or Gillespie, *how* did the autoimmune process continue for so long? Such questions were not persuasively answered by Petitioner. And the difficulty in diagnosing POTS is no justification for this failure. *See* Low at 353; Sheldon at e44. Petitioner simply failed to establish that (a) her POTS did begin close in time to the vaccination, or (b) if it did not, why the process took so long to reveal relevant symptoms.

III. Petitioner Has Not Established Entitlement Based on Her CFS Claim with Sufficient Preponderant Evidence

Before I discuss the *Althen* prongs for this aspect of Petitioner's claim, I will note that unlike Petitioner's claimed POTS injury, preponderant evidence better supports Petitioner's CFS diagnosis, although the strength of the evidence varies over time (a factor relevant to *Althen* prong three in particular). Dr. Fedele was persuasive in explaining why in her estimation Mrs. Yalacki's presentation (as of her first examination in January 2012) fit the criteria for CFS (leaving aside possible causes, or whether Petitioner's mental health status undermined the diagnosis). Earlier, other treaters (such as Dr. Pearson in October 2011) echoed that reaction, and although some contemporaneous treaters (in particular Dr. Cohen in July 2011) credibly pushed back against Petitioner's self-researched views about the nature of her illness, this could simply speak to the strength of the evidence in support of Petitioner's diagnosis at that particular time. Dr. Donofrio's review of the relevant diagnostic criteria did note sways in which Mrs. Yalacki's symptoms failed the overall CDC scheme for evaluating CFS, but his arguments were not enough to overcome Petitioner's preponderant showing on this issue (especially since the criteria for CFS are somewhat loose overall).

A. *Petitioner's Alleged CFS Has Not Been Preponderantly Shown to Be Vaccine-Caused*

Assuming that CFS can be caused by the Hep B vaccine,[45] I do not find in this case that Petitioner preponderantly established that *her* CFS was so caused. The same factual deficiencies with Petitioner's alleged POTS injury plague this aspect of her claim as well. Thus, in the months

[45] Because of the massive deficiencies in Petitioner's *Althen* prong two showing, she would not prevail even if I *did* find that she offered a plausible causation theory associating the Hep B vaccine with CFS. I therefore do not include in this decision a lengthy discussion of the strength of her *Althen* prong one showing with respect to CFS (and need not do so, as the Court of Federal Claims recognizes). *See W.C.*, 704 F.3d at 1358. However, Petitioner's theory in this regard had many of the same weaknesses as her arguments associating POTS to the Hep B vaccine. Thus, Dr. Shoenfeld's arguments were greatly undercut by Dr. Whitton's persuasive points about the limitations of molecular mimicry as explaining the pathologic mechanism herein, as well as the absence of reliable evidence (a) establishing that CFS is autoimmune-mediated (a conclusion even Dr. Shoenfeld did not fully embrace), and (b) explaining how an antigen derived from the Hep B vaccine would trigger the symptoms comprising CFS. In addition, case law in the Program suggesting that the Hep B vaccine can at least *contribute* to CFS does not also establish a more direct causal role.

after any treater first acknowledged that a CFS diagnosis might be accurate, Petitioner received several exams and evaluations, *none* of which provide any corroborative evidence (particularly in the form of a test result) that would suggest she was experiencing an autoimmune process consistent with Dr. Shoenfeld's causation theory. Indeed, treaters she saw within the first two months of vaccination—Drs. Jarrell, Cohen, and Mogyoros—openly dismissed her layman's views about the vaccination's association with her symptoms (with Dr. Mogyoros's records noting that Petitioner seemed uninterested in his informed medical opinion, which was based in part on testing he conducted). Ex. 2 at 68. These records similarly reveal that much of the impetus for the view that the vaccine was causal came from *Petitioner*, not treaters. *See, e.g.*, Ex. 2 at 146; Ex. 8 at 23. Even Dr. Moore, a treater who (without a substantial exam or workup) accepted the CFS diagnosis based on Petitioner's recitation of her history, expressed reluctance to identify the vaccine as causal, and in doing so was attacked by Petitioner. Ex. 2 at 359.

The other weakness in the "did cause" aspect of her CFS claim is the panoply of evidence suggesting that any CFS symptoms she experienced were more likely connected to her mental health struggles, which long predated her vaccination. The record plainly demonstrates that this possibility was raised by *several* treaters. *See, e.g.*, Ex. 2 at 87 (Dr. Burton's view in mid-June 2011), 124 (Dr. Jarrell's view at end of June 2011), 402–03 (Dr. Pearson's view that, at a minimum, symptoms might have some connection with mental health problems, and therefore mental health treatment would aid her CFS symptoms). Moreover, the pre-vaccination record also reflects the predominance of mental health problems—and so Petitioner's contentions that she was "stable" around the time of vaccination[46] have to be weighed not only against such professional views, but the entire medical record in this case (which records an individual excessively seeking medical treatment in connection with a vaccination she seems to have questioned within hours of its administration and reacting negatively to professional assessments that the vaccine was not likely the cause of her symptoms). While I am not finding an alternative cause for Petitioner's CFS symptoms (and make no attempt to diagnose her myself, as to do so falls well outside the scope of my role in this case), Petitioner's failure to rebut such extensive record evidence undermined the strength of her preponderant showing.

This record overwhelmingly does not support the conclusion that the Hep B vaccine played any role at all in Petitioner's CFS-related symptoms, and therefore the claim founders on the second *Althen* prong.

[46] The fact that Petitioner may temporarily have had certain mental health problems under control at the time of vaccination does not diminish their explanatory power in this case, especially given a medical record that reveals an individual compulsively seeking treatment and arguing with treaters who expressed opinions contrary to her personal beliefs about the nature of her injury.

B. *Petitioner Has Not Established that Her CFS Began in a Medically-Acceptable Timeframe After Vaccination*

Because the criteria for CFS are more flexible, the record provides some support for Petitioner's contention that her CFS symptoms (in particular, unusual fatigue) could have begun within two weeks of vaccination, as Dr. Shoenfeld argued. But the record reveals that Mrs. Yalacki had experienced intermittent bouts of fatigue and other related symptoms in the years *before* the vaccination that could also be deemed indicia of long-standing CFS that predated vaccination. Indeed, the pre-vaccination evidence supportive of CFS is *stronger* than the same evidence supporting Petitioner's POTS-based claim. Accordingly, it cannot be concluded in this case that her onset more likely than not post-dated vaccination—a critical aspect of *any* Program case. *Shalala v. Whitecotton*, 514 U.S. 268, 273–74 (1995).

Even if her pre-vaccination history is ignored, Petitioner was still unsuccessful in establishing both a likely post-vaccination onset date, as well as why it would be medically acceptable timeframe as measured from the June 2, 2011 vaccination date. As discussed above, Dr. Shoenfeld was inconsistent in identifying the onset for Mrs. Yalacki's CFS, and seemed of the opinion that *any* post-vaccination onset date would be reasonable—a sweeping contention that reads the third *Althen* prong out of the standard for causation entirely. Tr. at 191. Arguments that onset began in the first two weeks post-vaccination must be balanced against the fact that the treaters who saw Petitioner in the months immediately thereaftter persuasively rebutted the conclusion that her symptoms were vaccine-associated, let alone evidence of CFS. Indeed, this record does not support distinguishing between the symptoms Mrs. Yalacki claims to have *immediately* experienced post-vaccination (which even Dr. Shoenfeld would seem to allow were no more than expected post-vaccination malaise) and those later symptoms deemed the official onset.

The record is no more supportive of a slightly longer onset. Dr. Moore was the first treater to diagnose Petitioner with CFS, and she did so in late September 2011, so it could be argued that in fact Petitioner's CFS-associated symptoms began sometime in the intervening three-month period after vaccination. But whatever the date, Dr. Shoenfeld did not credibly or persuasively explain why such a timeframe would be medically acceptable under his theory—especially given this record, which does not allow for the conclusion that *any* autoimmune process was occurring in the summer of 2011. Nor did Petitioner establish that the treaters who saw her immediately around the time of vaccination were wrong—or that symptoms the record shows she plainly *believed* were evidence of a CFS-like illness were not.

At bottom, too many questions about onset and its relationship both to the timeframe from vaccination, as well as the course of Petitioner's CFS, exist in this case to find the third *Althen* prong was satisfied. If onset occurred close in time to vaccination, *how* was it that this process

continued on thereafter, unabated, into 2012 (with a substantial improvement period as well)? Why did immediate treaters reject the diagnosis? Why did testing from the summer of 2011 not support the conclusion that an autoimmune-derived illness existed? And how were later treaters like Dr. Fedele (who does not appear to have had the benefit of Petitioner's prior medical history when she diagnosed her, at least initially) more correct in their assessment? *See* Tr. at 96, 103, 106. Alternatively, if onset occurred more than one month post-vaccination, what is to be made of Petitioner's immediate claims of a reaction, and symptoms that sound like CFS (*e.g.*, Ex. 2 at 22–24, 34; Ex. 5 at 4–7)? Why are such immediate symptoms distinguishable from CFS but later ones are not?

CONCLUSION

Based upon the aforementioned analysis, I conclude that Mrs. Yalacki has not carried her burden of proof, and therefore I must DENY entitlement in this case.

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 accord with this decision.[47]

IT IS SO ORDERED.

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

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