In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-063V

FINNETTIA GARNER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Corcoran Dated: March 24, 2017 Decision; Ruling On the Record; Hepatitis A Vaccine; Hepatitis B Vaccine; Parsonage-Turner Syndrome; Onset.

Sean F. Greenwood, The Greenwood Law Firm, Houston, TX, for Petitioner.

Gordon E. Shemin, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION ON THE RECORD DISMISSING CASE[1]

Finnettia Garner filed a petition on January 22, 2015, seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] ECF No. 1 ("Pet."). Ms. Garner alleged that the Hepatitis A and B vaccines[3] she received in her left deltoid on December 13, 2011, caused her to develop a variety of injuries, including Parsonage-Turner Syndrome ("PTS"), as well as stomach ulcers, a fungal infection, and a damaged cornea. Pet. at 3-4.

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

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

[3] Petitioner also asserted that she received the typhoid vaccine at the same time (Pet. at 1; Ex. 2 at 2-3), but that is not a covered vaccine under the Vaccine Act and its applicable regulations, and therefore cannot be the basis for any entitlement award herein. 42 C.F.R. § 100.3(a).

After the parties filed expert reports, and based upon my initial review of the case record, I proposed that the matter be decided without holding an evidentiary hearing, and invited briefing on the substantive merits of Petitioner's claim. Having completed my review of the evidentiary record and the parties' filings, I hereby **DENY** Petitioner's request for compensation, for the reasons stated below.

I. Factual Background

On December 13, 2011, Petitioner (who was 44 years old at the time) received the Twinrix vaccine (a combination of the Hepatitis A and B vaccines) in her left deltoid, as well as a typhoid vaccination in her right deltoid. Ex. 2 at 2-3. The vaccines were required by Ms. Garner's employer because she was traveling to Angola for work purposes. Pet. at 1. The contemporaneous medical records are devoid of any mention of a subsequent reaction to the Twinrix vaccine – either immediately or in the ensuing four weeks.

Thereafter, on January 23, 2012, Petitioner traveled to Angola as planned. On January 27, 2012, 45 days after receipt of the vaccinations, Petitioner reportedly experienced severe pain emanating from her right shoulder (the opposite location of the Twinrix vaccine administration). Pet. at 1-2; Affidavit, dated March 16, 2016 (filed as ECF No. 21-1) ("Garner Aff.") at ¶ 5. Petitioner avers that the pain lasted ten days, followed by weakness that persisted another week or two. *Id.* There is no contemporaneous medical documentation of these symptoms, however, nor did Ms. Garner seek treatment for the pain and weakness. Ms. Garner explained that she opted to forgo treatment because she did not feel comfortable seeking it while abroad, and she also indicated that she had moderately improved after a few weeks, making medical intervention unnecessary. *Id.*

Three months passed, and then Petitioner obtained a physical examination on April 30, 2012 (now 139 days after receipt of the Hep A and B vaccines). The exam revealed nothing wrong with Petitioner that would reflect any prior illness or problems relating to her shoulder, and Ms. Garner made no mention of additional pain, weakness, or numbness of any kind during this doctor's visit. Ex. 13 at 2-4. Indeed, according to Ms. Garner's most recent affidavit, by this point in time she "no longer had pain or weakness in my arm and believed the incident in Angola was an isolated, single incident." Garner Aff. at ¶ 6. Significantly, between this April 2012 medical appointment and her receipt of the Twinrix vaccine in December 2011, Ms. Garner had never complained of any left-side (arm or shoulder) pain or weakness.

On June 15, 2012, Petitioner reported pain affecting her left shoulder that she maintained had begun the previous day. Ex. 5 at 1; Garner Aff. at ¶ 7. She thus sought treatment at HealthOne Emergency Center in Pearland, Texas. Ex. 5 at 1-6. X-rays of her left shoulder, taken on June 18

and 22, 2012, showed inferior subluxation[4] of the left humerus. Ex. 8C at 5. Orthopedic surgeon Anup Shah, M.D., proposed "possible" PTS as a diagnosis. Ex. 8A at 4. By now, over six months had passed since Petitioner's receipt of Twinrix, yet this was the first time she reported pain on her left side and the first pain of any such kind since her alleged experience while in Angola (although she has since stated that it was similar to what she had experienced at that time, albeit on a different shoulder). Garner Aff. at ¶¶ 6, 8. The records from these visits, however, merely state that her left-side pain had been persistent for approximately six months and say nothing about the pain changing sides. *See, e.g.,* Ex. 8A at 7.

Dr. Shah attempted to evaluate the nature of Ms. Garner's pain and its possible sources. On June 26, 2012, Dr. Howard Derman performed an electromyogram ("EMG")[5] and nerve conduction study ("NCS"),[6] both of which resulted in normal readings. Ex. 9 at 1-2. Dr. Derman specifically reported that Petitioner's lower arms showed no evidence of denervation, but her voluntary effort in contracting the muscles under examination was poor. *Id.* at 2. Petitioner returned for a follow-up with Dr. Shah on July 6, 2012, where she reported that her pain had improved by 40 percent. Ex. 8B at 1. Petitioner did display a limited range of motion in her left shoulder, however, and she had developed a rash under her arm due to her inability to lift it. *Id.* at 3. She was therefore referred to a dermatologist for the rash's examination. *Id*. Dr. Shah noted that the partial dislocation of her shoulder had improved on a subsequent x-ray, and he continued to assess Petitioner's condition as possible PTS. *Id.* He noted, however, that due to a technical error he could not view the prior EMG testing results on the disc provided to him. *Id.* There are no subsequent records suggesting that Dr. Shah ever reviewed those results thereafter to evaluate if they changed his tentative diagnosis.

In the ensuing months and years, Petitioner alleges that she experienced some additional injuries indirectly related to her PTS. Thus, Petitioner maintains that she injured her right cornea while attempting to replace her arm sling. Garner Aff. at ¶ 13. She visited her optometrist, Dr. Bui, on July 5, 2012. Ex. 11 at 7. The notes from this visit reflect that Petitioner reported a spot in her eye that was red and hurt. *Id.* She continued to follow-up with Dr. Bui about this pain, and the notes reflect that she experienced additional light sensitivity. *Id.* at 9. The examination notes do

[4] A subluxation is an incomplete or partial dislocation. *Dorland's Medical Dictionary* 1791 (32nd ed. 2012) (hereinafter *Dorland's*).

[5] An EMG is an electrodiagnostic technique for recording the extracellular activity of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation. *Dorland's* at 602.

[6] A nerve conduction study measures the speed of conduction of an electrical impulse through a nerve. The study can determine nerve damages and destruction. *Nerve Conduction Studies*, Health Library, Johns Hopkins Medicine, http://www hopkinsmedicine.org/healthlibrary/test_procedures/neurological/nerve_conduction_velocity_ncv_92,p07076/ (last visited Mar. 6, 2017).

not include anything about scratching her eye with a sling, however, but instead report that she injured her eye pulling weeds while waiting for a repairman. *Id.* at 9.

As Petitioner was still reporting pain and light sensitivity on July 27, 2012, she was referred to the Eye Center of Texas for a more thorough corneal evaluation. Ex. 11 at 13; Ex. 12 at 9. There, she reported redness and a "prick" feeling all day in her eye. Ex. 12 at 1. The examination noted an "early scar" on her cornea along with some staining. *Id.* at 8. On July 30, 2012, the ophthalmologist diagnosed Petitioner with recurrent corneal erosion ("RCE") secondary to trauma that occurred on July 3, 2012. Ex. 12 at 7.

Petitioner also sought treatment for her rash, and based on Dr. Shah's referral, saw a dermatologist, Dr. Betty Markham, on July 6, 2012. Ex. 8B at 8. Due to her shoulder dislocation, Ms. Garner had been unable to raise her arm for two weeks, and reported feeling like she had a burn under her arm. Dr. Markham diagnosed her with acute contact dermatitis candida (fungus) infection and prescribed medication and ointments for treatment. *Id.*

The filed medical records also report additional injuries or episodes of pain, although their relationship to the primary injury alleged in this claim is even more attenuated. For example, Petitioner was in a motor vehicle collision on January 2, 2013, and reported left shoulder and neck pain starting about 12 hours after the impact. Ex. 16 at 81-83. On examination, Ms. Garner reported pain with turning the neck, but no neurological abnormalities were detected after an evaluation, and neck x-rays showed no irregularities. *Id.* None of the treaters who examined Petitioner at this time linked her reported symptoms to either her December 2011 vaccine or the later-diagnosed PTS.

Almost one year later, around December 25, 2013, Ms. Garner experienced yet another episode of pain affecting her right shoulder. Ex. 1 at 3. She had a normal neurological examination at that time, however. Ex. 8C at 1-2. X-rays taken at this visit showed early osteoarthropathy.[7] *Id.* at 5. Dr. Shah diagnosed possible PTS based on these findings on December 27, 2013. *Id.* at 1. He also noted that Petitioner had experienced similar symptoms and pain approximately a year and a half earlier on her left side with "complete resolution." *Id.* at 3.

In 2014, Ms. Garner had several additional medical appointments at which examinations of her PTS and its status were conducted. *See, e.g.*, Ex. 16 at 9-13, 39-44. Ms. Garner did not report any ongoing or new pain, muscle, or joint problems at these appointments, however, and an examination revealed normal joints, bones, and muscles, as well as normal muscle strength and tone. *Id.* at 12, 41. Petitioner has averred that as recently as December 18, 2014, she experienced

[7] Osteoarthropathy is any disease of the joints and bones. *Dorland's* at 1345.

another episode of right arm pain similar to that alleged to have first occurred in January 2012, but that it subsided within ten days. Ex. 1 at 1, 3.

II. Expert Reports

A. Dr. Yehuda Shoenfeld

Dr. Yehuda Shoenfeld is Petitioner's sole expert, and he filed two reports in this matter. *See* Report, dated October 28, 2015, filed as Ex. 17 on November 13, 2015 (ECF No. 16) ("First Shoenfeld Rep."); Report, dated January 20, 2015, filed on April 14, 2016 (ECF No. 26) (not designated as exhibit) ("Second Shoenfeld Rep."). Dr. Shoenfeld opined that the Hep A and B vaccines Petitioner received caused her PTS and related "incidents," including her inability to raise her arm.

Dr. Shoenfeld is currently the head of the Center for Autoimmune Diseases, which he founded at the Sheba Medical Center in Israel. Ex. 17 at 1 ("Shoenfeld CV"). He also serves as the research chair of autoimmune diseases at Tel Aviv University. *Id.* His experience focuses on autoimmune and rheumatic diseases, and he has published many peer-reviewed papers in journals and books on these topics. *Id.* He is on the editorial board of 32 journals in the field of autoimmunity. *Id.* He has not been identified as an expert on PTS or similar kinds of conditions, however.

Dr. Shoenfeld's first report examined Petitioner's relevant medical history before turning to his theory of causation. First Shoenfeld Rep. at 4. As Dr. Shoenfeld explained, PTS is a rare disorder characterized by an abrupt onset of shoulder pain, followed by weakness and atrophy of the upper extremities, requiring months to years to recover. *Id.* at 7. Its origination stems from the interaction of "genetic predisposition, mechanical vulnerability and an autoimmune trigger." *Id.* No tests currently exist to definitively confirm or exclude PTS. *Id.* Dr. Shoenfeld suggested that there is an overlap between PTS and brachial neuritis, which he asserted can also develop after receipt of certain vaccines. *Id.*

Dr. Shoenfeld then examined case studies of situations in which a link was shown between certain vaccines and neuropathic injuries. First Shoenfeld Rep. at 7-8. These studies included an infant who developed femoral neuroapraxia after Tdap/inactivated poliovirus/haemophilus influenza type B vaccinations; a 40-year-old man who developed GBS symptoms after a tetanus-toxoid vaccination; and a man who presented with demyelinating neuropathy after a tetanus-toxoid vaccination. *Id.* He also noted the possible links of Tdap to neuropathies and Transverse Myelitis ("TM") – a central nervous system ("CNS") condition in which inflammation causes

demyelination to CNS nerves – though none of these vaccinations are at issue in the present case, and demyelination is not implicated as a component of Ms. Garner's PTS herein. *Id.* Dr. Shoenfeld also described these neurological complications after Tdap to be "relatively infrequent" events where individual genetic predispositions might be a more significant causal factor. *Id.*

About halfway through his report, Dr. Shoenfeld proposed that one of the vaccines at issue in Petitioner's case – the Hep A vaccine – had the capacity to induce an autoimmune response. First Shoenfeld Rep. at 9. In connection with this assertion, he referenced a study (Karali et al., *Autoimmunity and Hepatitis A Vaccine in Children*, 21 J. Investigative Allergol. Clin. Immunol. 389:389-93 (2011) ("Karali"))[8] involving 40 children vaccinated with two doses of the Hep A vaccine. *Id.* The subjects were then studied for autoantibodies, which would signal the existence of an autoimmune response to the vaccine. *Id.* Anti-nuclear antibodies (ANAs) were detected in four children, and the presence of the autoantibodies following vaccination in these subjects was found to be statistically significant at a level of .002. *Id*. Dr. Shoenfeld also highlighted a different reported case of an individual who received the inactivated Hep A vaccine after recovering from a "self-limiting" hepatitis illness. *Id.* The man's condition deteriorated after this vaccination, and he developed autoimmune hepatitis, with a finding that ANAs were present. *Id.*

Dr. Shoenfeld next briefly referenced studies that he alleged demonstrate the autoimmune nature of the Hep B vaccine. First Shoenfeld Rep. at 9-10. These include multiple sclerosis, GBS, and neuropathy, among other conditions that have been linked to that vaccine – although Dr. Shoenfeld admitted that many of the links were based solely on case reports, thus limiting the probative value of such evidence. *Id.* at 10. Significantly, neither brachial neuritis nor PTS was included in the chart Dr. Shoenfeld provided of possible Hep B autoimmune reactions. *Id.*

Dr. Shoenfeld then turned to proposing possible mechanisms by which the Hep A and/or Hep B vaccines could cause PTS – but he began with a discussion of the relationship between the Hep B vaccine and TM. First Shoenfeld Rep. at 12. He listed several possible autoimmune mechanisms for Hep B vaccine-induced TM: 1) molecular mimicry between infectious antigens and self-antigens; 2) epitope spreading, whereby invading antigens accelerate an ongoing autoimmune process by local activation of antigen-presenting cells and over-processing of antigens; and 3) infectious agents, which can induce autoimmunity via polyclonal activation of B lymphocytes or bystander activation that then enhances cytokine production and induces the expansion of auto-reactive cells. *Id.* at 13. He further opined that adjuvants contained in the vaccines (intended to prompt a greater immune response) could also possibly help induce autoimmunity. *Id.* This theory Dr. Shoenfeld termed "Adjuvant Induction of Autoimmune

[8] Though Dr. Shoenfeld referenced Karali in his report, Petitioner never filed the article as an exhibit. I obtained a copy of the article for review; however, I have not discussed it in detail as it does not affect my overall opinion of the case.

Disease," or "ASIA." He noted that the aluminum adjuvant found in the Hep B vaccine could cause motor neuron death, weakness, autoimmune manifestations (such as the presence of autoantibodies), and neurological manifestations (such as the loss of myelinated nerve fibers). *Id.* at 13-14.

Dr. Shoenfeld went on to propose that the length of time between Petitioner's vaccination and the development of her PTS was medically appropriate. First Shoenfeld Rep. at 14. In so arguing, he relied on Ms. Garner's recollection that she had developed severe pain in her right shoulder (while in Angola) 45 days after the receipt of her vaccinations. *Id.* He referenced a list of cases of TM following vaccination – taken from another article never filed in this action[9] and based on no instances involving the Hep A or B vaccines – which observed a range of two days to nine years between vaccination and onset of TM. *Id.* at 14-15. From this, he determined that 45 days was medically appropriate, based on his prior assertion that Petitioner's PTS was autoimmune in character. *Id.*

Petitioner filed a supplemental expert report from Dr. Shoenfeld (after striking the initial filing due to incorrect exhibit attachments (ECF No. 23)) on April 14, 2016, which largely sought to address points raised in Respondent's expert report prepared by Dr. Eric Lancaster. Dr. Shoenfeld disagreed with Dr. Lancaster's assertion that PTS was an incorrect diagnosis. Second Shoenfeld Rep. at 4. Instead, Dr. Shoenfeld argued that Petitioner's treating doctor, Dr. Shah, was in the best position to examine Petitioner and diagnose her illness, which, augmented by Ms. Garner's own assertions about her medical history, suggested to him that PTS was the correct diagnosis. *Id.*

The supplemental report attempted to defend molecular mimicry as a possible causation mechanism. Second Shoenfeld Rep. at 6. To that end, Dr. Shoenfeld contended that molecular mimicry was a plausible scientific mechanism for diverse autoimmune conditions, and that the Hep B vaccine's proteins could constitute mimics for many antigens in the brain, nerves, spinal cord, and other organs. *Id.* For this assertion Dr. Shoenfeld relied on the paper, Ricco et al., *Hepatitis B Virus and Homo Sapiens Proteome-wide Analysis: A Profusion of Viral Peptide Overlaps in Neuron-Specific Human Proteins*, 4 Biologics 75:75-81 (2010), which he argued documented the possible Hep B vaccine mimics.[10] *Id.* Dr. Shoenfeld further sought to rebut Dr. Lancaster's contention that the molecular mimicry process could not be involved with PTS, which Dr. Lancaster proposed occurs rapidly (i.e. within 24-hours). *Id.* at 8. Dr. Shoenfeld noted that Ms.

[9] *See* Agmon-Levin et al., *Transverse Myelitis and Vaccines: A Multi-Analysis*, 18 Lupus 1198:1198-1204 (2009) ("Agmon-Levin").

[10] This article, like Agmon-Levin, was also not filed as an exhibit. Because my determination does not turn on whether the Hep B vaccine's proteins are sufficiently homologous to self-tissues to cause an autoimmune reaction, however, I do not discuss it at length herein, although I have examined it.

Garner had received Twinrix once a year from 2008 to 2011, and thus "plenty of time passe[d] for inducing autoantibodies that, in the course of the repeated [Twinrix] vaccine stimulations, could become autoantibodies" likely to react in a damaging fashion. *Id.*

Finally, Dr. Shoenfeld also addressed his ASIA theory in response to concerns I expressed during the case (as detailed below) about its legitimacy. Second Shoenfeld Rep. at 10. He emphasized that he mainly set forth the ASIA theory to explain the conditions under which molecular mimicry would occur (through stimulation of the immune system) – but also "as a potential explanation for the approximate 6 weeks between Petitioner's vaccination and onset of her symptoms." *Id.* Dr. Shoenfeld otherwise maintained ASIA's scientific validity, pointing out that new research and studies since released support his theory, offering (although not filing) 611 citations in medical literature to the ASIA syndrome. *Id.* at 10. He purported that these citations demonstrate the theory's current popularity in the medical field. *Id.* He also specifically referenced 24 articles (published concurrently or after other special masters' decisions criticizing the ASIA theory) that he claimed supported this theory despite criticism. *Id.* at 11. Out of these 24 articles, Dr. Shoenfeld co-authored 16, although he filed only two in this particular case. *Id.* He also noted that he has recently been invited to give lectures on the ASIA theory at the American College of Rheumatology and European Congress of Rheumatology. *Id.* at 10.

B. Dr. Eric Lancaster

Dr. Eric Lancaster provided one expert report in response to Dr. Shoenfeld. *See* Report, dated December 31, 2015, filed as Ex. A (ECF No. 18) on January 15, 2016 ("Lancaster Rep."). Dr. Lancaster questioned PTS as the correct diagnosis, and otherwise challenged Petitioner's allegations that her symptoms (whatever their nature) could have been caused by the Twinrix vaccine.

Dr. Lancaster is a clinical doctor at the Center for Autoimmune Neurology at the University of Pennsylvania, as well as an assistant professor of neurology at the University of Pennsylvania. Ex. B at 1 ("Lancaster CV"). He completed a neurology residency at the University of Pennsylvania from 2004-07. *Id.* His research focuses on antibody-mediated neurological disorders, and he sees patients with complex autoantibody disorders on a regular basis. *Id.* He has personally treated five to ten patients with PTS, or brachial plexitis, including two with recurring attacks. Lancaster Rep. at 3.

Dr. Lancaster first reviewed Petitioner's medical history before turning to an explanation of the brachial plexus and PTS. Lancaster Rep. at 3-8. As he notes, the brachial plexus is located between the spinal nerve roots and the nerves of the arm and relates to the sensory and motor function of the upper extremities. *Id.* at 8. The brachial plexus can be injured in many ways,

including trauma or infection, which causes weakness or numbness. *Id.* at 8-9. Brachial plexitis is the general term for injury to the plexus due to inflammation, while any other kind of unexplained plexitis is commonly called PTS. *Id.* at 9. PTS often involves a finding of winged scapula due to involvement of the long thoracic nerve, and it also generally involves selective weakness of the muscles of the anterior interosseous nerve. *Id.* PTS is also referred to as neuralgic amyotrophy, to signify that it is characterized by severe pain, muscle weakness, and atrophy. *Id.*

As Dr. Lancaster further explained, the course of PTS can be distinguished from brachial neuritis. PTS generally has a duration of four weeks, and it is hard at first glance to distinguish from other types of shoulder and neck pain (such as cervical radiculopathy, a torn rotator cuff, or a dislocated shoulder). Lancaster Rep. at 9. Once initial pain wears off, a detailed neurological examination can be performed that will show weakness and numbness in a pattern detailing the parts of the plexus that were injured. *Id.* There will also be atrophy over the next several weeks to months. *Id.* Any recovery of strength after a PTS attack will be slow and take many months to years, in Dr. Lancaster's opinion. *Id.* at 10. Abnormalities in the muscle would continue to persist "forever," even after recovery. *Id.*

Because of its nature, motor nerve damage caused by PTS would be apparent on an EMG, according to Dr. Lancaster. Lancaster Rep. at 10. Any decrease in affected sensory responses would also be permanent and would show up on a nerve conduction study, as injured axons cannot generally grow back. *Id.* Accordingly, in Dr. Lancaster's view, a PTS diagnosis would be doubtful in the presence of normal EMG/NCS studies. *Id.*

Dr. Lancaster went on to discuss his understanding of possible causes of PTS. In his view, PTS has numerous triggering events – most commonly trauma to the shoulder, post-operative cases (often themselves attributable to body positioning), or simply sitting or lying in an uncomfortable position for a long period of time. Lancaster Rep. at 10. Dr. Lancaster has thus personally treated patients for PTS experienced immediately (within 24 hours) after surgery or after long plane flights. *Id.* Though he acknowledged the existence of literature observing the inflammatory nature of PTS and possible autoimmune mechanisms for its occurrence, its tendency toward rapid onset diminished the likelihood that it was exclusively autoimmune in etiology, since this would be too fast to attribute to an immune response. *Id.*

Relying on the foregoing, Dr. Lancaster disputed the accuracy of Ms. Garner's PTS diagnosis. He noted that in none of her reported episodes of shoulder pain was there any documentation of weakness (a symptom he believed was central to the condition). Lancaster Rep. at 11. Additionally, there were no reports of atrophy subsequent to the episodes of pain, nor documentation of patterns of sensory loss or persistent numbness as would be expected with PTS. *Id.* He also noted that the only EMG/NCS study performed was normal, thus conflicting with the

usual presentation of PTS. *Id.* And Ms. Garner made no mention of any other typical PTS symptoms, such as weakness, at her April 2012 doctor's appointment – even though an individual then suffering from PTS that had begun a little more than two months prior would likely be experiencing such symptoms. *Id.* at 7. Because of this lack of testing corroboration or clinical indicia, Dr. Lancaster did not agree that any of Petitioner's individual attacks represented any form of brachial plexitis. *Id.* Further, he thought it was unlikely that she would suffer multiple attacks of PTS without these additional signs. *Id.*

Dr. Lancaster proposed alternative explanations for Petitioner's pain in her shoulders, such as her left shoulder dislocation as documented on x-rays. Lancaster Rep. at 11. Petitioner's symptoms also could have been tied to her plane trip to Africa, a more likely cause than a vaccination received 45 days prior. *Id.* at 12. Dr. Lancaster reported personally witnessing at least one "attack" of PTS that was apparently triggered by a transpacific flight. *Id.* He noted that other common causes of PTS were not explored in Petitioner's case. *Id.* at 11.

Dr. Lancaster then turned to Petitioner's arguments about a link between Twinrix and her symptoms. He acknowledged that brachial plexitis has been linked to vaccination, and noted that brachial neuritis can also manifest on the side of the body opposite to that of the site of vaccine administration. Lancaster Rep. at 12. But he noted that neither the Hep A nor B vaccines had ever been so associated. *Id.* Indeed, the 2011 Institute of Medicine ("IOM") report found no evidence that the Hep B vaccine could cause PTS, and the Hep A vaccine was not even discussed (suggesting the plausibility of a relationship to PTS even less in the case of that vaccine). *Id.* (citing Stratton et al, *Adverse Effects of Vaccines: Evidence and Causality* (2011), filed as Ex. A Tab 6 ("2011 IOM Report")).

Dr. Lancaster went on to dispute specific components of Dr. Shoenfeld's report that attempted to apply circumstances in which other vaccines, such as the TDaP vaccine, caused other autoimmune neurologic disorders to the present case, arguing that they in fact were irrelevant since they involved distinct conditions with different pathophysiologies. Lancaster Rep. at 13-14. He also questioned the reliability of the studies making such links. *Id.* at 14. For similar reasons, he rejected Dr. Shoenfeld's cited case studies that purported to show a relationship between the Hep A or Hep B vaccines and different diseases or conditions not comparable to PTS, like TM. *Id.*

Besides discussing the general reliability of Dr. Shoenfeld's theory, Dr. Lancaster attacked the specific mechanisms Dr. Shoenfeld proposed for causation, such as molecular mimicry, as implausible. He particularly took issue with the facially sweeping character of Dr. Shoenfeld's opinion, which seemed to suggest molecular mimicry as the applicable mechanism for virtually all autoimmune conditions. *See* Lancaster Rep. at 14, First Shoenfeld Rep. at 12-13. If so, the Hep B

vaccine would have to have a mimic for antigens in several different organs – something Dr. Lancaster deemed unlikely. Lancaster Rep. at 14.

Finally, Dr. Lancaster discussed the timing component of Petitioner's theory as reflected in Ms. Garner's actual history. He opined that there was no reliable evidence that molecular mimicry could be a mechanism for PTS, which was commonly characterized by a rapid onset of symptoms (*e.g.* within a day). Lancaster Rep. at 14. Molecular mimicry would take far longer to occur, as he understood the process. *Id.* More generally, in Dr. Lancaster's reading of the literature, the maximum latency between vaccination and an associated PTS case is four weeks. *Id.* at 12 (citing Stratton et al., *Evidence Bearing on Causality*, *Adverse Events Associated with Childhood Vaccines,* Institute of Medicine Report (1994), filed as Ex. A Tab 5 ("1994 IOM Report")). The 45 days from vaccination in this case to Ms. Garner's initially-reported symptoms was thus too long to be causally related.

III. Procedural History

As noted above, Petitioner originally filed this action in January 2015. Pet. at 1, 3-4. She then filed medical records related to her treatment in February and March of 2015. ECF No. 7-8. Respondent thereafter filed her Rule 4(c) Report on June 22, 2015, asserting that Petitioner was not entitled to compensation because she could not carry her burden of proof. Respondent's Rule 4(c) Report (ECF No. 10). Specifically, Respondent alleged that it was unclear what diagnosis the medical records actually supported. *Id.* at 8. Further, Respondent noted that Petitioner had not provided a reliable medical theory or logical sequence of cause and effect, as none of the treating physicians associated her symptoms with her vaccines and the time period of 45 days between vaccination and onset of symptoms had not been demonstrated to be medically appropriate to infer vaccine causation. *Id.* at 8-9.

After an extension of time, Petitioner filed her first expert report from Dr. Shoenfeld on October 30, 2015. ECF No. 15. She then refiled this same report on November 13, 2015, labelling it as Ex. 17. ECF No. 16. Thereafter, Respondent filed an expert report from Dr. Lancaster on January 15, 2016. ECF No. 18. In response, Petitioner filed an affidavit clarifying facts that she felt were incorrectly represented in Respondent's expert report. ECF No. 21.

Due to concerns over Dr. Shoenfeld's ASIA theory, I asked Petitioner during a status conference held on February 4, 2016, to provide a supplemental report from Dr. Shoenfeld stating to what extent he was relying on this theory, and explaining how the theory was still viable in light of other special masters' decisions. As I noted at that status conference, the special masters have questioned the validity of the ASIA theory, expressing the view that it is, at a minimum, incomplete and preliminary – and therefore unreliable from an evidentiary standpoint. *See, e.g., D'Angiolini*

v. Sec'y of Health & Human Servs., No. 99-578V, 2014 WL 1678145 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (determining that the ASIA theory did not meet the minimum threshold for reliability and thus could not be a reliable basis for compensation), *mot. for review den'd*, 122 Fed. Cl. 86 (July 2, 2015), *aff'd*, 645 Fed. App'x 1002 (Fed. Cir. 2016); *Rowan v. Sec'y of Health & Human Servs.*, No. 10-272V, 2014 WL 7465661 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) (rejecting the ASIA theory as it is not a proven theory and the mechanism whereby adjuvants could cause autoimmune illness is not known), *mot. for review den'd*, 2015 WL 3562409 (Fed. Cl. June 9, 2015))

In response, Petitioner filed a second expert report from Dr. Shoenfeld on April 14, 2016, again after multiple extension requests. ECF No. 26. Respondent also filed the relevant medical literature associated with Dr. Lancaster's first report on April 12, 2016. ECF No. 25.

Thereafter, I held a status conference to discuss my opinion that, based on the materials filed in the matter, live testimony at a hearing would not be required. Order, dated April 15, 2016 (ECF No. 27). Petitioner filed her motion for a ruling on the record on July 30, 2016. ECF No. 28 ("Motion"). Respondent filed her response on September 16, 2016 (ECF No. 30) ("Opp."), to which Petitioner replied on October 14, 2016. ECF No. 31 ("Reply"). The matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner's Motion argues that she is entitled to compensation because she has satisfied her burden of proof. In response to questions about the locus of Petitioner's initial symptoms, which did not manifest in the arm where the Twinrix vaccine was administered, she contends that PTS manifests bilaterally in one-third of cases. *Id.* at 5. Petitioner then maintains that she has provided a reliable causation theory, based upon Dr. Shoenfeld's explanation for how the Twinrix vaccine could cause PTS, and the biological mechanisms by which this would occur. *Id.* at 7. Petitioner also asserts that she has reasonably relied upon her expert's references to literature and studies showing that vaccines can cause PTS or other, comparable autoimmune conditions. *Id.* at 8-9. Petitioner further contends that the timing of her post-vaccination injuries was medically appropriate: she was diagnosed with PTS after vaccination, and Dr. Shoenfeld provided references to medical literature (mainly involving TM) that vaccines can cause autoimmune conditions such as PTS within the timeframe at issue. *Id.* at 8-9.

Respondent opposes the Motion, arguing that Petitioner's evidentiary showing is inadequate to carry her burden. Opp. at 1. First, Respondent maintains that PTS is likely an incorrect diagnosis because there is no evidence of atrophy, persistent weakness, or numbness in the contemporaneous medical records, and she had a normal EMG/NCS study. *Id.* at 7. Next, assuming PTS is the correct diagnosis, Respondent questions the reliability of Petitioner's

causation theory. *Id.* at 8. Applicable medical literature does not associate the Hep A or B vaccines with PTS, and the fact that those vaccines can cause different autoimmune conditions does not support Petitioner's contention that they could similarly cause PTS, a distinguishable condition. *Id.* at 8-9. Respondent further rejects Petitioner's assertion that molecular mimicry could be the mechanism, as there was no demonstrated known antigen to be mimicked. *Id.*

Respondent also attacks Petitioner's conclusion that there was a "logical cause and effect" relationship between vaccine and injury. Opp. at 10. Thus, although Petitioner alleges she had experienced PTS, there was never a showing of which nerves were injured, which muscles developed the expected atrophy and weakness, and no showing of abnormalities on electrodiagnostic testing, thus no corroborative proof that the vaccine "did cause" the alleged injury. *Id.* at 10. At the same time, other potential explanations existed for Ms. Garner's condition that Petitioner did not adequately take into account, including a partial dislocation, a car accident, and a long plane flight, as well as possible cervical radiculopathy. *Id.* at 10-11. Finally, Respondent proposes that 45 days between vaccination and onset is too long to be medically appropriate, given what is known about PTS (which would typically manifest sooner). *Id.* at 11.

Petitioner's Reply mostly reiterates the arguments previously advanced in her opening motion. Reply at 5-8. She acknowledges that her own testimony about initial symptoms was insufficient to support a finding of entitlement, but argues that, if read in conjunction with the medical records, there is enough evidentiary support to find in her favor. *Id.* at 3. She also notes that because this matter is being resolved on the papers, credibility determinations that might support her interpretation of the fact history cannot be made. *Id.* at 4. She does not, however, otherwise argue against a ruling on the record as a reasonable means of resolving this case.

V. Legal Standards

A. Claimant's Burden in Vaccine Program Cases

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

[11] 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

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

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

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, 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

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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).

statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

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 den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

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

B. Law Governing 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"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is

based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 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. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). 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 Pharm., Inc*., 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial 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 her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (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 den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

D. Consideration of Medical Literature

Petitioner's expert filed some medical and scientific literature in this case, including articles offered in support of her causation theories. *See generally* ECF No. 26, 29. I have reviewed all of the medical literature filed[12] in this case, although my decision does not discuss each filed article in detail. *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). A write-up or summary of each within the body of this decision is not called for, however, in explaining my disposition of Petitioner's claim.

E. Determination to Resolve Case Without Hearing

I have opted to decide entitlement based on written submissions and evidentiary filings, including both side's expert reports, and neither side has objected to my proposal. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.,* No. 15-085, 2016 WL 7664475, at *25-28 (Fed. Cl. Spec. Mstr. Nov. 28, 2016),

[12] Notably, out of 61 articles referenced in Dr. Shoenfeld's two expert reports, only four were filed. While in a few such cases (the Agmon-Levin article, for example), I have discussed or considered an unfiled item because of its apparent significance to Petitioner's theory and/or my resolution of her claim, I have not reviewed every single unfiled citation – and am not otherwise obligated to do so, consistent with the fact that Program claimants are not required to produce medical literature to establish causation. *See Capizzano*, 440 F.3d at 1324; *Althen*, 418 F.3d at 1280. It is otherwise a petitioner's responsibility to file and/or raise with the special master those items that he or she deems important enough to constitute evidence in his or her favor. *See, e.g., Cedillo*, 617 F.3d at 1347 (special master did not err in disregarding articles where no experts gave any testimony as to the "validity or import" of such article).

mot. for review den'd, _____ WL _____, slip op. at 13-15 (Fed. Cl. Mar. 2, 2017); *Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.,* 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns,* 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.,* No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

Having reviewed the record and evaluated the competing expert reports, I find that Petitioner has not carried her overall preponderant burden of establishing it "more likely than not" that the Twinrix vaccine caused her PTS, or any of the proximately-caused injuries or symptoms related to the same. None of the three prongs under the Federal Circuit's test for non-Table causation claims established in *Althen* has been satisfied in this case.

A. Petitioner has Not Established a Medically Acceptable Timeframe for her PTS

In this case, analysis of the strength of Petitioner's showing requires concurrent consideration of the proof offered in support of the first and third *Althen* prongs. This reasonably flows from the close relationship between the two. *See, e.g., de Bazan*, 539 F.3d at 1352 (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)); *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013).

If I consider only the first, "can cause" prong in isolation, Petitioner's theory that Hep A and/or Hep B vaccines could cause PTS has some reliability. To begin with, literature filed in this case (by Respondent, no less) persuasively links other vaccines to PTS. *See* Feinberg et al., *Parsonage-Turner Syndrome*, 6 Hospital for Special Surgery 199:199-200 (2010) (filed as Ex. A Tab 2) ("Feinberg") (noting that the tetanus toxoid; diphtheria, pertussis, tetanus vaccine; smallpox; and "other" vaccines have been associated with the development of PTS). In addition, the Hep A and B vaccines have been credibly associated with other autoimmune conditions (although the autoimmune character of PTS has not been all that persuasively established by

Petitioner).[13] There is also some relevant Program authority concluding that the Hep B vaccine could cause brachial plexus neuritis (a form of PTS). *See, e.g.*, *Hall v. Sec'y of Health & Human Servs.*, No. 02-1052V, 2007 WL 3120284 (Fed. Cl. Spec. Mstr. Oct. 4, 2007).

In addition, while I do not find the ASIA component of Petitioner's theory that Dr. Shoenfeld presented persuasive (for the same reasons that other special masters have rejected it),[14] Dr. Shoenfeld did propose another plausible mechanism for how the Twinrix vaccine could cause PTS: molecular mimicry. Molecular mimicry is a widely accepted mechanism in the Vaccine Program when applied to immune-mediated conditions and could plausibly explain the development of PTS. *See, e.g.*, *Tompkins v. Sec'y of Health & Human Servs.*, No. 10-261V, 2013 WL 3498652, at *22 (Fed. Cl. Spec. Mstr. June 21, 2013) ("[t]he molecular mimicry theory is the one most widely accepted for the agents most frequently accepted as causal"), *mot. for review den'd*, 117 Fed. Cl. 713 (2014). Many autoimmune conditions have been thought to have molecular mimicry as an underlying mechanism. *See, e.g., Doe/29 v. Sec'y of Health & Human Servs.*, 2009 WL 180078 (Fed. Cl. Spec. Mstr. Jan. 21, 2009) (molecular mimicry causing demyelinating disease after Hepatitis B vaccination); *Lilley v. Sec'y of Health & Human Servs.*, No. 09-31V, 2009 WL 3320518 (Fed. Cl. Spec. Mstr. Sept. 28, 2009) (Hepatitis B causing GBS and chronic inflammatory demyelinating polyneuropathy through the mechanism of molecular mimicry). And in any event, proving a specific biological mechanism is not required of Program petitioners as part of establishing their causation theory. *Knudsen*, 35 F.3d at 548-49.

Petitioner's theory begins to breaks down, however, when consideration is given to the proposed timeframe in which it is theorized PTS could occur after receiving the Hep A or B vaccines – or did, in Ms. Garner's case. Assuming the facts in the light most favorable to Petitioner, Ms. Garner alleges that (a) she experienced vaccine-induced PTS beginning 45 days from vaccination, (b) her pain completely subsided such that she did not require treatment, but then (c) it flared up again nearly five months later, when she was for the first time formally diagnosed with PTS. But there has been no showing at all of how PTS could take such a waxing and waning course. Petitioner has similarly not provided any medically plausible explanation for how molecular mimicry could begin, stop, and then continue occurring, with no signs or medically documented proof six months after vaccination. Conclusory reasoning on Dr. Shoenfeld's part that this is possible – rather than by offering literature or evidence – is not sufficient to make this showing.

[13] Similarly, Petitioner over-relies on comparisons with other vaccines and their relationship to TM – a disease unquestionably characterized by demyelination, which has not been shown herein to be a feature of PTS.

[14] *See, e.g., D'Angiolini*, 2014 WL 1678145; *Rowan*, 2014 WL 7465661.

The theory collapses even if I narrow my consideration to the 45-day window between vaccination and Ms. Garner's purported initial symptoms while abroad. The literature and other cases where molecular mimicry has been deemed the mechanism for an injury after vaccination suggest that an autoimmune response would more likely than not occur in a shorter time period. For instance, in an article filed by Petitioner, the usual development of clinical manifestations of GBS (an autoimmune condition) following vaccination is within one to three weeks (although Program decisions have found it can occur in a slightly longer timeframe under certain conditions). Blank et al., *Molecular Mimicry and Auto-Immunity*, 1 Clinical Reviews in Allergy and Immunol. 111:111-118 (2007) (ECF No. 26-5).[15] PTS itself would likely occur far sooner, as Dr. Lancaster persuasively established, given its most common causes. *See* Lancaster Rep. at 10, 12; Feinberg at 199-200; *see also Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (citing *de Bazan*, 539 F.3d at 1352) (the "etiology" of a disorder determines the appropriate temporal relationship). This is true even if instances in which vaccine-induced PTS or brachial neuritis are considered. 1994 IOM Report at 71-72; Lancaster Rep. at 13. Petitioner's own filed literature shows that PTS/brachial neuritis often has a sudden (i.e. measured in days) onset of severe pain after the triggering injury or vaccination. *See* Robinson et al., *Brachial Neuritis Following a Corticosteroid Injection*, BMJ Case Rep., at *2 (2014) (filed as ECF No. 29-1) (patient developed severe pain two days after injection).

Petitioner was unable to establish the propriety of the proposed 45-day timeframe with any literature or case studies of her own. Rather, Petitioner's primary support for finding 45 days to be temporally appropriate is a comparison to cases of vaccine-associated TM, as set forth in a Table included in Dr. Shoenfeld's report that was in turn taken from an unfiled article, Agmon-Levin. First Shoenfeld Rep. at 14 (citing Agmon-Levin at 1200). But even if 45 days would be temporally appropriate for some vaccine-caused instances of a different disease, the same is not a given with respect to PTS, which has a different pathophysiology (and in particular has not been shown to involve demyelination like TM – the illness addressed in the Agmon-Levin chart). More fundamentally, the Agmon-Levin chart reproduced in Dr. Shoenfeld's report appears to rely on unsubstantiated case studies, and moreover proposes such a wide range of onset time periods that it is almost facially useless in aiding my determination.[16]

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[15] In Vaccine Program cases, the usual onset of GBS has been described to range from a few days to no more than six weeks. *See, e.g.*, *Burchett v. Sec'y of Health & Human Servs.*, No. 12-119V, 2014 WL 2465194, at *15 (Fed. Cl. Spec. Mstr. May 13, 2014) (noting that both experts agreed that in recurrent GBS cases, onset happens within a few days to six weeks); *Glassberg v. Sec'y of Health & Human Servs.*, No. 07-303V, 2009 WL 4641696, at *7 (Fed. Cl. Spec. Mstr. Nov. 23, 2009) (accepting both experts' testimony that GBS onset within six weeks after vaccination could be causally related to the vaccination); *Tyson v. Sec'y of Health & Human Servs.*, No. 90-3379V, 1997 WL 702562, at *10 (Fed. Cl. Spec. Mstr. Sept. 30, 1997) ("it is clear from the medical literature and the medical testimony that the *typical* range for onset of GBS symptoms following the triggering event is five days to six weeks").

[16] I also take note of Petitioner's failure to file Agmon-Levin as having some impact upon the weight I give it. Special masters are not required to consider articles that a petitioner fails to either submit or bring to the Court's attention as

Dr. Shoenfeld's ASIA theory does not appreciably bulwark Petitioner's arguments about the medical appropriateness of the timing of her post-vaccine injury. As I noted to Petitioner earlier in the case, ASIA has been reasonably criticized by other special masters, who have noted that it defines virtually any length of time passing between vaccine receipt and injury as medically appropriate – a concept antithetical to the legal rationale for the third *Althen* prong. *Johnson v. Sec'y of Health & Human Servs.*, No. 10-578V, 2016 WL 4917548, at *10 (Fed. Cl. Spec. Mstr. Aug. 18, 2016) ("accepting this argument would force the undersigned to render *Althen*'s third prong toothless, and it is therefore invalid on its face"); *Hennessey v. Sec'y of Health & Human Servs.*, 91 Fed. Cl. 126, 142 (2010) (rejecting Dr. Shoenfeld's attempt to satisfy the third prong by positing that any timeframe is appropriate). Accordingly, the lengthy timeframe at issue herein cannot be saved by such questionable (at least at this point in time) science.

In light of the above, even if I accept that the Hep A or B vaccines could cause PTS in some circumstances, I do not find that they could do so in the timeframe at issue *in this case* – or, more broadly, in the stuttering manner that Ms. Garner's actual symptoms are alleged to have occurred.

B. *Althen* Prong Two

I also do not find that Petitioner has presented preponderant evidence to satisfy the second *Althen* prong. The second *Althen* prong requires a Vaccine Act claimant to establish a logical explanation of how the vaccine actually caused injury under the relevant facts. *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). But there are problems both with Petitioner's favored diagnosis, PTS, as well as the extent to which the medical record does not conform to, or contradicts, Petitioner's causation theory.

First, and as noted above, Respondent has raised a number of valid and unrebutted objections to the propriety of Dr. Shah's PTS diagnosis. Opp. at 7. As Dr. Lancaster persuasively opines in his report, Petitioner lacked the required clinical indicia or other testing results (muscle atrophy or persistent weakness, normal EMG/NCS study, etc.) that would confirm Dr. Shah's June 2012 diagnosis (which was somewhat tentative in any event). *Id.* In addition, the records reveal

significant. *Cedillo*, 617 F.3d at 1347 (not error for special master to disregard piece of scientific literature not raised as significant by petitioner). I gave some consideration to Agmon-Levin because I needed to understand the underpinnings of the chart in Dr. Shoenfeld's report, which he seemed to rely upon to support the contention that the timing of onset of Ms. Garner's PTS was medically appropriate. But Petitioner has not bothered to defend it or justify its use herein, and I need not root around for a reason to give it greater weight without some effort by Petitioner to explain to me *why* that is the case.

that Dr. Shah's proposed diagnosis was without the benefit of certain highly relevant evidence, such as the EMG results, that might have caused him to reconsider. *See* Exs. 8A at 4, 8B at 3 (noting that Dr. Shah could not review the EMG results). Also lurking in those same records is a credible explanation for Ms. Garner's June 2012 pain – her shoulder dislocation – that the records do not reveal was ever fully explored by treaters, but which was noted to have improved by July (at the same time that Ms. Garner's pain began to diminish). Exs. 8B at 3, 8C at 5.

It is the case that the PTS diagnosis never appears to have been rejected, at least based on the limited medical history and materials filed in this case. *See, e.g.,* Ex. 8A at 4; Ex. 8B at 3; Ex. 8C at 1. Moreover, the diagnosis came from a contemporaneous treater, whose views merit some weight in my determination. I am therefore reluctant to find (especially since this matter is being resolved based on my review of the record alone) that the evidence absolutely does not support the diagnosis (even though I do not find that Petitioner has fully defended it).[17]

But the paucity of evidence supporting the PTS diagnosis is nevertheless harmful to Petitioner's case – especially when the period from December 2012 until the time of the diagnosis six months later is considered in its entirety. Here, Ms. Garner's medical records do not contain any proof that an autoimmune process was underway, or that her initial symptoms were most likely attributable to PTS, until June 2012 at the earliest. Ex. 5 at 1. Indeed, Petitioner was seen by a doctor in April 2012, but there was no mention in those records of any pain Petitioner was experiencing at that time, or any mention of the pain she allegedly experienced in her right arm[18] in January (contrary to Dr. Lancaster's recitation of what an individual suffering from PTS would likely have experienced). Ex. 13 at 2-4. Her months-long recovery afterward also belies the likelihood that she experienced PTS as soon as she has alleged – only for it to completely vanish by April, then reappear in June.

This raises yet another problem with Petitioner's claim – the other, plausible explanations for her condition. Petitioners are required to establish that the relevant vaccine was the "but for" cause of their injury. *See, e.g., Pafford*, 451 F.3d at 1356; *Shyface*, 165 F.3d at 1352-53. Here, as

[17] In particular, Dr. Lancaster's explanation of PTS and the clinical indicia or testing results that he would associate with it were more credible and persuasive than those offered by Dr. Shoenfeld. Although Dr. Shoenfeld is clearly an extremely experienced and credentialed immunologist with ample expertise to opine on behalf of Petitioner with respect to her causation theory, he lacks the same grounding in neurological injuries, coupled with day-to-day expertise in diagnosing them, demonstrated by Dr. Lancaster.

[18] Petitioner's allegation that a vaccine received in her left arm could cause an injury to begin in her other arm (the situs of a non-covered vaccine) also raises problems with her claim. However, as Dr. Lancaster himself acknowledged, brachial neuritis linked with a vaccine can develop in either arm, regardless of vaccination site. Lancaster Rep. at 15 (citing 1994 IOM Report); *see also Baldonado v. Sec'y of Health & Human Servs.*, No. 06-521V, 2009 WL 734088, at *6 (Fed. Cl. Spec. Mstr. Feb. 25, 2009) (petitioner's brachial neuritis onset began in left arm and then developed in his right shoulder – although the pain began in the same arm as his vaccination site). I therefore do not find that the migration of symptoms from the right to left arm necessarily rebuts her claim.

Respondent notes, in addition to her shoulder dislocation, there are other reasonable explanations for her claimed initial symptoms in February, such as her international travel. It is just as likely that Petitioner's PTS developed after some other triggering event that happened temporally closer to her symptoms in June 2012, or even January 2012 for that matter (a trip abroad to Africa involving lengthy air travel) – and there are no medical records, test results, or other evidence that would suggest a vaccine reaction was occurring prior to that date.

There are other deficiencies in the record that undermine the conclusion that Ms. Garner's symptoms were vaccine-caused. None of Petitioner's treating physicians proposed a link between her condition and her vaccines, even though she was treated several times for her arm pain over an almost three-year period. As a treating physician would have been aware of Petitioner's circumstances, the fact that not one mentioned any vaccination link suggests that no treater considered it to be a factor related to Petitioner's condition or illness. And no treaters ever provided an explanation for the stuttering course that her PTS allegedly took.

CONCLUSION

The Vaccine Act permits me to award compensation only if a petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. The medical record in this case reveals that Petitioner's injury is too far removed from the time of vaccination to plausibly suggest a link between the two, nor has Petitioner presented a persuasive or reliable causation theory that fits the facts. There is therefore insufficient evidence to support an award of compensation, and I must hereby **DISMISS** this claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[19]

IT IS SO ORDERED.

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

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