In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-948V

Filed: August 7, 2017

ROBERT T. MITCHELL,	*	PUBLISHED
Petitioner,	*	
v.	*	Dismissal; Tetanus-Diphtheria Vaccine; Insufficient Proof of Causation
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Randall G. Knutson, Esq., Knutson & Casey Law Film, Mankato, MN, for petitioner.
Glenn A. MacLeod, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT[1]

Roth, Special Master:

On December 3, 2013, Robert Mitchell ("Mr. Mitchell" or "petitioner)" filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner alleges that the Tenivac tetanus diphtheria vaccination[3] he received on October 14, 2012, caused him to suffer from "fever, extreme muscle

[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 in 42 U.S.C § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, 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, this decision will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] In his filings, petitioner and his expert repeatedly, and incorrectly, assert that petitioner received the "DTap" vaccination. *E.g.*, Pet. 1; Pet. Ex. 28 at 1. According to the Express Care immunization report, Petitioner actually received the Tenivac vaccination. Pet. Ex. 3 at 3. Tenivac consists of tetanus and diphtheria toxoids absorbed onto aluminum phosphate; it does not contain the pertussis toxoid found in the DTaP (diphtheria-tetanus-acellular pertussis) vaccination. *See* Full Prescribing Information at 14, TENIVAC, https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152826.pdf.

spasms, [and] sequela of which was vertigo and pervasive myositis." *See* Petition ("Pet."), ECF No. 1.

Upon review of the evidence submitted in this case, the undersigned finds that petitioner has failed to carry his burden of showing that he is entitled to compensation under the Vaccine Act. In particular, petitioner has failed to show that he suffered an identifiable injury rather than mere symptoms of an unknown injury, and that any of these symptoms were caused by the vaccination he received. The petition is accordingly dismissed.

I. Medical and Procedural History

A. Petitioner's Health Prior to the Allegedly Causal Vaccination

Petitioner was born on February 2, 1951. Petitioner's pre-vaccination medical history is significant for prostate cancer, hypertension, gastroesophageal reflux disease, high cholesterol, chronically low potassium, Attention Deficit Disorder, arthritis, malaise and fatigue. Pet. Exs. 2, 4, 15. In November of 2007, petitioner was involved in a car accident that resulted in soft tissue injuries to his neck, back, and shoulders. Pet. Ex. 13 at 1.

In February of 2009, petitioner sought chiropractic treatment for complaints of neck and back pain, numbness and tingling on his right side, tightness in his back, and spasms. Pet. Ex. 13 at 1. Between February of 2009 and October of 2012, petitioner presented to the chiropractor more than 80 times for treatment of these complaints. *See id.* In September of 2012, petitioner presented to his primary care physician, Dr. Vernon Rubick at North Springs Family Medicine ("North Springs"), complaining of knee pain as well as "other malaise and fatigue." Pet. Ex. 9 at 15; Pet. Ex. 15 at 1-2.

On October 14, 2012, petitioner presented to Express Care Plus ("Express Care"), in Colorado Springs, Colorado, complaining of a dog bite to his right hand that occurred two days prior.[4] Pet. Ex. 3 at 4, 48. He was diagnosed with cellulitis and prescribed antibiotics. Petitioner also received the allegedly causal Tenivac tetanus diphtheria vaccination. *Id.* at 3-8.

B. Petitioner's Health Following the Allegedly Causal Vaccination

Five days after receiving the vaccination, on October 19, 2012, petitioner returned to Express Care for follow-up on his dog bite. Pet. Ex. 3 at 10. He was afebrile and denied any systematic symptoms. *Id.* at 10-11. His sole complaint was abdominal pain due to the antibiotics. *Id.* at 10. Two days later, on October 21, 2012, petitioner returned to Express Care complaining of back and neck spasms, which were treated with a nonsteroidal anti-inflammatory

[4] There is some discrepancy in the medical records as to the exact date and nature of this claim. Most of the records indicate that petitioner suffered a dog bite; however, an entry from his chiropractor on October 24, 2012, notes that petitioner "fell and cut [his] right hand." Pet. Ex. 13 at 45. Moreover, while most of the records state that this dog bite occurred on October 12, 2012, others indicate that it occurred on October 11, 2012. *See* Pet. Ex. 4 at 16; Pet. Ex. 9 at 14.

injection. *Id.* at 13-14. On October 24, 2012, petitioner visited his chiropractor complaining of neck spasms. Pet. Ex. 8 at 1.

Seven days later, on October 31, 2012, petitioner returned again to Express Care, and was seen by Dr. Mark Walton. Pet. Ex. 3 at 15-17. Petitioner reported that, since he received the vaccination, he "ha[d] been getting cramps all over his body" and that "[w]alking, sitting, arising from lying to sitting[,] sitting to standing all cause extreme spasms in his neck, his arms[,] his legs, lower back, and calves." *Id.* at 15. He denied experiencing any dizziness, headaches, or head pain. *Id.* Petitioner was concerned "that the tetanus shot may have given [him] an active case of tetanus." *Id.* Because petitioner's complaints exceeded the scope of an outpatient facility, Dr. Walton referred him to the emergency room at Penrose St. Francis Medical Center for further evaluation. *Id.* at 16.

Petitioner presented to Penrose's Emergency Department the next day, on November 1, 2012. Pet. Ex. 4 at 7. He told the nurse that, a few days after he received the vaccination, he "develop[ed] full body muscle spasms, mostly back," as well as a low-grade fever. *Id.* at 16. The emergency room physician noted that petitioner's "host of complaints" was "somewhat confounding"; he was "confus[ing] his pain with weakness"—e.g., claiming "that he 'could not walk'" even though "he was able to manage to get out of bed and get dressed[,] attend with activities of daily living and drive a car here for an evaluation." *Id.* Petitioner appeared to be in no physical distress except for the sharp pain in his neck and left knee. *Id.* at 16-17. An x-ray of petitioner's knee showed moderate knee effusion and mild degenerative changes. *Id.* at 17. Petitioner's lumbar spine x-ray revealed slight scoliosis, curvature of the spine, and mild degenerative disc and joint changes. *Id.* His blood work showed a high white blood cell count of 15,800. *Id.* at 18. Joint fluid was collected from his left knee, but showed no crystals and no organisms on a gram stain. *Id.* His electrolyte levels were unremarkable and his creatinine phosphokinase level[5] was 109, well within the normal range of 48-308. *Id.* at 38. Petitioner was given Tylenol and observed for several hours. *Id.* at 18, 28-33. Thereafter, petitioner was "no longer having intermittent muscle spasm," and he stated that "his pain [was] somewhat improved." *Id.* at 18. He was sent home with Tylenol and told to follow up with his primary care physician. *Id.*

On November 2, 2012, petitioner followed up with Dr. Jennifer Linden at North Springs. Pet. Ex. 9 at 2, 12. Petitioner stated that he "developed generalized muscle aches and spasms" after his vaccination. *Id.* at 14. He reported "no muscle weakness[,] no numbness/tingling," "no fever," "no loss of consciousness, no weakness, no dizziness, and no headaches" at that visit. *Id.* (emphasis omitted). It was noted that petitioner was limping due to left knee pain. *Id.* at 15. He requested and was prescribed muscle relaxers, which accompanied Dr. Linden's assessment of "unspecified" "myalgia and myositis." *Id.* at 14-15. Dr. Linden also prescribed antibiotics for the dog bite. Petitioner claimed that his "symptoms 'improved' while taking an antibiotic" initially. *Id.* at 15. He was told to return to North Springs the following day for a follow-up. *Id.*

[5] Creatine phosphokinase is a muscle enzyme that is often elevated in patients with myositis or other muscular inflammatory conditions. *See, e.g.*, Georgina Espígol & Josep M. Grau, *Polymyositis*, in *Diagnostic Criteria in Autoimmune Diseases* 149, 150-51 (Yehuda Shoenfeld et al. eds., 2008).

Petitioner returned to North Springs for a follow-up on November 3, 2012, and presented to Dr. Rubick. *Id.* at 9-11. Petitioner stated that, while the antibiotic medication helped, he was still experiencing "muscle aches (left neck), arthralgia/joint pain (left knee, improving), and back pain (improved), but no muscle weakness or numbness/tingling." *Id.* at 10-11. He reported "no weakness, no dizziness, and no headaches or fatigue." *Id.* at 11. His body temperature was 98.2 degrees. *Id.* According to the record, the "work up to this point ha[d] been negative, and his physical symptoms continue[d] to improve"; thus, Dr. Rubick concluded that he had "no further work up to offer" and that he would refer petitioner to a specialist if symptoms did not continue to improve. *Id.* at 12. Dr. Rubick's assessment noted petitioner as having "pain in joint; lower leg" and "cervicalgia."[6]

Four days later, on November 7, 2012, petitioner presented to Dr. Walton at Express Care. Pet. Ex. 3 at 18. Dr. Walton reported that, by petitioner's "own admission, the symptoms ha[d] subsided dramatically without any further intervention." *Id.* Dr. Walton concluded that his examination of petitioner was "entirely unremarkable." *Id.* at 19. He found "mild atrophy of the patellar area laterally in the left lower extremity" and noted that, although petitioner "ha[d] a full range of motion in this extremity," it was "painful for him." *Id.* Dr. Walton's ultimate diagnosis was "joint pain multiple sites." *Id.* Petitioner requested and received a reference to an orthopedist. *Id.*

On November 13, 2012, petitioner presented to his chiropractor with "all over body aches and pains," "histamine response to Tetanus shot," and "pain [and] swelling in knee[,] worse on left." Pet. Ex. 8 at 1.

The next day, on November 14, 2012, petitioner completed an intake form for the Colorado Springs Orthopedic Group. Pet. Ex. 5 at 1. Petitioner reported that he was experiencing pain, instability, weakness, and swelling in both knees, and that the "problem or issue start[ed]" on August 1, 2012. *Id.* Specifically, he stated that he had been experiencing these symptoms for four months in the right knee and one month in the left knee. *Id.* In the section marked "Medical History," petitioner stated "Muscle Spasms (severe due to T-Dap shot)"; in the section marked "Allergies," he stated "T-Dap Shot: Myositis."[7] *Id.* at 8.

Petitioner met with Dr. Michael Huang at the Colorado Springs Orthopedic Group on November 16, 2012. *Id.* at 9. Dr. Huang noted that petitioner believed that his left knee pain "may be related to polymyositis which may have occurred after a DTaP vaccination reaction." *Id.* Petitioner and Dr. Huang discussed possible treatment options and decided on aspiration and injection, which Dr. Huang believed "would particularly help if this is an autoimmune type phenomenon." *Id.* at 10. The fluid aspirated from petitioner's knee was not sent for analysis. *Id.* Dr. Huang concluded that petitioner's "left knee had a very large effusion" and

[6] Cervicalgia refers to pain in the neck. *Dorland's Illustrated Medical Dictionary* 47, 333 (Saunders eds., 32nd ed. 2012) (*Dorland's*).

[7] Myositis is "inflammation of a voluntary muscle." *Dorland's* 1225. Polymyositis is "a chronic, progressive myositis with symmetrical weakness of the limb girdles, neck, and pharynx; it can occur in either children or adults." *Id.* at 1490.

"question[ed]" whether it had any "relation to polymyositis or autoimmune type disease." *Id.* There were "no clear signs of infection." *Id.*

Petitioner presented to his chiropractor on November 21, 2012, and reported "that sharp pain has decreased and that all over body aches are gone." Pet. Ex. 8 at 2. He returned to his chiropractor five additional times between November 21, 2012, and January 4, 2013. *Id.* at 2-4.

On January 9, 2013, petitioner presented to a nurse practitioner at Express Care, reporting dizziness, fatigue, and weakness. Pet. Ex. 3 at 20. He denied having arthritis, joint pain, or muscle or joint stiffness. *Id.* He was diagnosed with "dizziness/vertigo" and "nausea." *Id.* at 21. During the visit, petitioner began to slide out of his chair, and an ambulance was called. *Id.* Petitioner "began experiencing sporadic muscle twitches upon arrival of EMS." *Id.* The EMTs noted that petitioner was alert, able to speak in full sentences when they arrived, and able to move himself from the exam room table to their gurney. Pet. Ex. 10 at 10. Upon his arrival to the emergency room, petitioner underwent a CT scan and an EKG, and both were negative. *Id.* Petitioner reported that "[h]is pain level is a 0[,] . . . other than a leg which has some residual symptoms from the myositis diagnosis associated with the symptoms he had described . . . 3 months ago." *Id.* at 40. The emergency room doctor diagnosed petitioner with an "acute episode of vertigo" and prescribed meclizine[8] with instructions to follow up with Dr. Rubick. *Id.* at 41.

On January 13, 2013, Petitioner presented to Linda Steimling, a physician's assistant at North Springs. Pet. Ex. 9 at 7. Petitioner reported that he continued to have vertigo and mild nausea, and that the meclizine was making him tired. *Id.* at 9. Petitioner also reported having left knee pain and swelling. *Id.* Physical therapy was suggested to help petitioner with his vertigo, but petitioner declined and stated he would get treatment from his chiropractor. *Id.*

Petitioner presented to his chiropractor on January 14, 2013, with complaints of slight nausea, dizziness, neck pain, and left calf pain. Pet. Ex. 8 at 4. He returned on January 21, 2013, with complaints of neck pain and stiffness but stated that the pain in his left calf had improved. *Id.*

Petitioner returned to Dr. Rubick on January 29, 2013, to follow up on his lab results from the emergency room. Pet. Ex. 9 at 4-7. Petitioner stated he was still feeling dizzy and unsteady. *Id.* at 6. Dr. Rubick referred petitioner to Danielle Spivey, a physical therapist, for vestibular therapy. *Id.* Ms. Spivey noted that petitioner reported "[v]ertigo and imbalance dating back to October 2012 where he reports his health completely changed after having a TDaP injection." Pet. Ex. 11 at 1. Petitioner also reported to Ms. Spivey that "the TDaP injection caused him to have Myositis which he reports is an autoimmune disease process." *Id.* Ms. Spivey concluded that petitioner did *not* have vertigo. *Id.* at 2. She did, however, find that petitioner had nystagmus.[9] *Id.* Ms. Spivey also suggested that petitioner's complaints could be

[8] Meclizine is an "antihistamine used in the management of nausea, vomiting, and dizziness associated with motion sickness and of vertigo associated with disease affecting the vestibular system; administered orally." *Dorland's* 1117.

[9] Nystagmus is "an involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotatory, or mixed, i.e., of two varieties." *Dorland's* 1307.

attributed to his neck and that "with the Myositis he has had significant muscle spasms throughout his body, which include his neck." *Id.* She noted that "Myositis is not a diagnosis I am very familiar with and he reports it is Autoimmune, but I honestly don't know that myself." *Id.* She recommended that petitioner complete Vestibular Ocular Reflex exercises at home and return in 2-4 weeks for a follow up. *Id.* Petitioner presented to his chiropractor on February 1, 2013, and February 15, 2013, complaining of back and neck spasms. Pet. Ex. 8 at 5.

Petitioner returned to Ms. Spivey on February 26, 2013. Pet. Ex. 11 at 5. Petitioner reported that his dizziness and balance had improved with the prescribed exercises. *Id.* Ms. Spivey noted that the exercises were helping petitioner, both according to his own accounts and objectively upon examination. *Id.*

On March 14, 2013, petitioner wrote to several Express Care physicians requesting a letter stating that the vaccination he received caused his symptoms. Pet. Ex. 3 at 36. Petitioner's letter indicated his intent to file a claim under the Vaccine Program. *See id.* ("I have an opportunity for partial reimbursement from a court in Washington DC to recover some costs. It is not a lawsuit, it is a vaccination claims center. I need your professional opinion that the vaccination I received caused an auto-immune response, which allowed the myositis to enter and create havoc within my body."). Dr. Walton responded with the following letter:

> I am in receipt of your letter dated 3/14/2013. I certainly do remember the symptoms you were having when I first saw you. As I stated to you at that time I have never seen anything similar to the problem you were experiencing. It is very interesting that the possibility of an allergic reaction to the TDAP injection could have caused this. I have never seen a reaction like this to the vaccine before so I cannot unequivocally state that this was the origin of your symptoms. Apparently Dr. Rubick feels that this may have been an auto-immune response and he may be correct. I have sent you what information I could find including the package insert from the drug company itself. I put [an] arrow next to the only statement that even remotely resembles what might have happened. I apologize for not being able to do more but I wish you all the best and hope you're doing better.

Id. at 37.

On April 1, 2013, petitioner presented to Dr. Rubick with complaints of muscle aches, weakness and dizziness. Pet. Ex. 9 at 2-3. Dr. Rubick recommended that petitioner continue vestibular therapy with Ms. Spivey. *Id.* at 4. Petitioner asked Dr. Rubick to write him a letter opining that the vaccination he received was associated with his symptoms. *Id.* Dr. Rubick noted, "Although I informed the patient that I can't make a 100% association with the TDaP immunization and his symptoms, I will write a letter stating that it could 'possibly' be associated." *Id.* Dr. Rubick wrote the following letter dated April 27, 2013:

> I am writing this letter for a patient at their request. Mr. Mitchell was given a prophylactic immunization (TDap) at another provider's office on 10/14/2012. It was soon after administration of this immunization that Mr. Mitchell began to have adverse reactions. The most prominent being severe body aches/myalgias. Mr.

> Mitchell asked if, in my opinion, the reaction could be related to the TDaP immunization [he] received. It is "in my opinion" reasonable that the patient's myalgia complaints were related to his TDaP immunization, although there is no possible way to 100% definitively make this connection. Apparently, Mr. Mitchell may get some financial assistance in regards to medical expenses that arose from this "reaction" if some causation is identified. Again, I feel it is reasonable to make this association between [petitioner's] symptoms, and administration of the TDaP vaccine.

Pet. Ex. 7 at 1.

Petitioner returned to Ms. Spivey for a third visit on April 8, 2013, complaining that he "veers to the left when walking." Pet. Ex. 11 at 7. Ms. Spivey noted that petitioner continued to use the word "vertigo" to describe his symptoms but that, because petitioner was "not at all spinning nor dizzy," she explicitly instructed him to stop using that term because it was inaccurate. *Id.* She also noted petitioner's reports that his "neck pain ha[d] been very significant with his Myositis." *Id.* Ms. Spivey recommended that petitioner continue the gaze stabilization exercises she prescribed and to follow up. *Id.*[10]

On April 30, 2013, petitioner presented to Dr. Monique Giroux at the Movement and Neuroperformance Center. Pet. Ex. 6 at 1. His primary complaint was "myositis, vertigo." *Id.* Upon examination, Dr. Giroux found that petitioner suffered from "muscle spasms, imbalance, [and] loss of stamina of unclear etiology." *Id.* She also noted that "[s]tress may be playing a role as well." *Id.* She prescribed Baclofen[11] for petitioner's muscle spasms and recommended that he return for a follow-up in three weeks. *Id.* Petitioner returned to Dr. Giroux on May 15, 2013, and she continued to treat his reported neck tightness and imbalance with Baclofen. Pet. Ex. 17 at 1-2.

On May 7, 2013, petitioner returned to Ms. Spivey. Pet. Ex. 11 at 9. He reported no improvement of his veering to the left while walking. *Id.* Ms. Spivey noted, "I really think I have done all I can to help Mr. Mitchell, as his balance is quite good and he is educated on postural exercises. Perhaps he could attend a trial of PT to address his neck and shoulder pain with one of our orthopedic PTs." *Id.* at 10.

Petitioner returned to Ms. Spivey on June 20, 2013. Pet. Ex. 8 at 7; Pet. Ex. 19 at 1. At this visit, Ms. Spivey noted that petitioner brought recent bloodwork results for review, *see* Pet. Ex. 9 at 52-55; however, she explained that she was not qualified to review bloodwork and that her "role was to address his dizziness or imbalance which has improved." Pet. Ex. 19 at 1. She discussed with petitioner the potential benefits of physical therapy for his cervical spine and neck pain caused by his myositis. *Id.* She referred petitioner to physical therapist Francis DeKalb. *Id.*

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[10] Between March and April 2013, petitioner also visited his chiropractor four times complaining of neck spasms. *See* Pet. Ex. 8 at 6-7.

[11] Baclofen is a muscle relaxer and antispastic that is used to treat spasticity of the spinal and cerebral origin. *Dorland* 191.

Petitioner presented to Mr. DeKalb on June 28, 2013, for physical therapy, reporting that he had neck spasms and stiffness with a limited range of motion. *Id.* at 3. Mr. DeKalb performed transcutaneous electrical nerve stimulation ("MHP/TENS") on petitioner's cervical spine to reduce pain and spasms, and performed cervical tractions, passive range of motion, and joint mobilization to improve his mobility. *Id.* Petitioner presented to Mr. DeKalb again on July 2, 2013, and reported that he was doing much better. *Id.* at 4. Petitioner attended physical therapy sessions with Mr. DeKalb once a week through December 16, 2013, and generally reported "feeling better" with some stiffness and dizziness. *See id.* at 5-30.

On July 10, 2013, petitioner returned to Dr. Giroux at Movement and Neuroperformance Center for a follow-up. Pet. Ex. 17 at 3. Petitioner continued to complain of muscle spasms, stiffness, neck pain, dizziness, and vertigo (improved). *Id.* Dr. Giroux increased petitioner's Baclofen, gave him a lidocaine patch for pain, Botox injection for neck spasms and pain, and recommended that petitioner continue with physical therapy. *Id.* Dr. Giroux noted that petitioner had left side muscle pain, but had good range of motion and his balance and gate had improved. *Id.* at 4. Thereafter, petitioner sought treatment from Dr. Giroux about once a month from July 2013 through November 2013. *See* Pet. Ex. 17 at 5-11; Pet. Ex. 25 at 1. Dr. Giroux treated petitioner's neck pain and stiffness with Botox injections and Baclofen. *Id.* On September 11, 2013, petitioner returned to Dr. Giroux for neck pain. Dr. Giroux noted that petitioner's "muscle spasm, imbalance, dizziness and loss of stamina of unclear etiology" have "[a]ll dramatically improved." Pet. Ex. 17 at 11.

On January 9, 2014, petitioner presented to Express Care for a routine physical, and was seen by Dr. Gary Tarshis. Pet. Ex. 16 at 5. It was noted that petitioner continued to complain of severe muscle spasms. *Id.* Dr. Tarshis noted that this was a "complicated case," that petitioner "had been to [the] ER twice" and was "now under the care of a neurologist in Denver,"[12] and that petitioner "was told he had 'myalgias.'" *Id.* Petitioner repeated his belief that "there might be a causal relationship with his Tdap 5 days before this began." *Id.* Dr. Tarshis listed a diagnosis of muscle spasms and hyperlipidemia. *Id.* at 7.

Petitioner received another physical examination by Dr. Mark Smith at North Springs on April 30, 2014. Pet. Ex. 21 at 6. He complained of difficulty urinating, and he denied any weakness, dizziness, muscle aches, muscle weakness, arthralgia/joint pain, back pain, or swelling. *Id.* at 6-7. On May 4, 2014, petitioner presented to Linda Steimling for a follow up of his lab results. *Id.* at 1-4. Petitioner had "[n]o complaints." *Id.* at 4.

On September 8, 2014, petitioner presented to Dr. Giroux with a complaint of muscle spasms and a "new problem [of] 'brown out' with stooping over." Pet. Ex. 23 at 1. Petitioner's Baclofen was decreased and he was told to follow up in three months. *Id.*

On December 3, 2014, petitioner presented to North Colorado Springs Primary Care to discuss his hypertension. Pet. Ex. 26 at 4-5. Petitioner presented with dizziness as a secondary complaint, and denied any issue with neck and musculoskeletal system. *Id.* at 5-6, 11.

[12] No records from a neurologist in Denver were filed.

On December 8, 2014, petitioner presented to Dr. Giroux for a follow up. Pet. Ex. 23 at 3. It was noted that, in the prior few weeks, his neck stiffness had worsened and his balance was an issue, but it was stable. *Id.* He was given a Botox injection and told to follow up in three months. *Id.*

Petitioner presented to Dr. Rubick on March 23, 2015, for a physical exam. Pet. Ex. 26 at 15. Petitioner continued to have hypertension, which was chronic but well controlled. *Id.* He complained of occasional fatigue, but denied having any headaches or neck pain. *Id.* at 25. Dr. Rubick also noted chronic hyperlipidemia and gastroesophageal reflux disease. *Id.* at 25-26. Petitioner followed up with Dr. Rubick on April 8, 2015 regarding the results of his lab reports. *Id.* at 34. After reviewing the results, Dr. Rubick recommended that petitioner follow up with his urologist and modify his diet to help control his glucose levels. *Id.*

Petitioner returned to Dr. Giroux for another botox injection on May 5, 2015, where it was noted that petitioner's muscle spasms, imbalance, dizziness, and loss of stamina of unclear etiology had been "dramatically improving." *Id.* at 5. However, petitioner stated that he still had brief episodes of blackouts and a tendency to veer left when walking. *Id.* It was also noted that petitioner had no long-term sequela and that his balance remained an issue but was stable. *Id.* Upon examination, Dr. Giroux noted "pain over posterior neck and lower hamstring" and "walking with head turns all normal without ataxia or veering movements." *Id.* at 6.

On June 4, 2015, petitioner presented to Dr. Diane Hesselbrock at Neurosciences Center at Memorial Hospital for evaluation of "black out" spells. Pet. Ex. 24 at 29. It was noted that petitioner complained of muscle spasms following the October 2012 vaccination that "have improved, but about a year ago, he started having frequent 'black or brown out' spells." *Id.* Petitioner stated that he was prescribed Baclofen; however, it "ma[de] him dizzy." *Id.* Dr. Hesselbrock reviewed petitioner's workup, including a brain MRI and an MRA, and noted that petitioner's symptoms may be associated with dyspnea.[13] *Id.* She suggested he speak with his primary care physician regarding a possible cardiac assessment. *Id.*

Finally, throughout 2015 and 2016, petitioner continued to seek treatment from his chiropractor for his back and neck pain as well as his physical therapist for his dizziness and abnormal gait. *See generally* Pet. Ex. 24 (chiropractor); Pet. Ex. 25 (physical therapist).

C. Expert Reports

1. Petitioner's Expert: Dr. Dahlgren

Petitioner filed an expert report from Dr. James Dahlgren on August 7, 2015. *See* Pet. Ex. 28. Dr. Dahlgren graduated from University of California, San Francisco and is board certified in internal medicine. He completed a residency in internal medicine, followed by a two-year fellowship in infectious disease at UCLA Medical Center. He is currently in private

[13] Dyspnea is "breathlessness or shortness of breath." *Dorland* 582

practice in internal medicine and occupational and environmental medicine, with a specialty in toxicology. Pet. Ex. 29.

According to Dr. Dahlgren, petitioner "has classic ASIA (i.e. autoimmune/inflammatory syndrome induced by adjuvants)[,] a syndrome that can be induced by vaccination containing adjuvants." Pet. Ex. 28 at 7. He opined that petitioner "probably has what is known as Macrophagic Myofasciitis (MMF), a subset of ASIA caused by aluminum salts in vaccines." *Id.* According to Dr. Dahlgren, aluminum adjuvants "are a potent immune system stimulator," and "[i]n some susceptible people the aluminum over-stimulates the immunes [sic] system and causes the immune system to attack the person. Mr. Mitchell is one [of] those unfortunate people." *Id.* at 8. Dr. Dahlgren does not point to any specific medical testing or records to support this proposition, but suggests that petitioner's "illness is consistent with the medical conditions linked to tetanus vaccination in several studies." *Id.* at 7-8.

Dr. Dahlgren referenced several studies that can be grouped into two categories. First, he cites two studies—*Santiago et al.*[14] and *Exley et al.*[15]—for the proposition that vaccinations containing aluminum adjuvants may trigger MMF. *See id.* at 8-10. As noted above, MMF is an alleged subset of ASIA, a theory widely associated with Dr. Yehuda Shoenfeld. In his benchmark paper in 2011,[16] Dr. Shoenfeld reviewed the four "enigmatic conditions" that comprise ASIA, one of which is MMF. The central premise of ASIA is that these conditions are the result of an adjuvant effect resulting in the development of some autoimmune or auto-inflammatory disease in humans. *See id.* at 9-10; *see also D'Angiolini v. Sec'y of Health & Human Servs.*, No. 99-578V, 2014 WL 1678145, at *57-58 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (describing the origins of and medical criteria for the ASIA theory), *aff'd, rev. denied*, 122 Fed. Cl. 86 (2015), *aff'd*, 645 F. App'x 1002 (Fed. Cir. 2016).

Second, Dr. Dahlgren relies on several studies for the broader proposition that aluminum adjuvants can cause some adverse response, whether autoimmune, neurological, or inflammatory. He cites *Luján et al.*,[17] a sheep study that "revealed that aluminum adjuvants at low doses is tolerated but repeated or high doses of aluminum adjuvants cause a serious autoimmune, neurological and inflammatory disease." Pet. Ex. 28 at 8. Dr. Dahlgren also relies on *Khan et al.*,[18] which found that "aluminum persisted in distant organs one year after intramuscular injection of alum-containing vaccine." *Id.* at 9. This study, Dr. Dahlgren states, also "notes that aluminum adjuvant used in vaccines can migrate to the brain and cause damage

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[14] Tânia Santiago et al., *Macrophagic Myofasciitis and Vaccination: Consequence or Coincidence?*, 35 Rheumatology Int'l 189 (2015).

[15] Christopher Exley et al., *A Role for the Body Burden of Aluminum in Vaccine-Associated Macrophagic Myofasciitis and Chronic Fatigue Syndrome*, 72 Med. Hypotheses 135 (2009).

[16] Yehuda Shoenfeld & Nancy Agmon-Levin, *'ASIA' – Autoimmune/Inflammatory Syndrome Induced by Adjuvants*, 36 J. Autoimmunity 4 (2011).

[17] Lluís Luján et al., *Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants (ASIA Syndrome) in Commercial Sheep*, 56 Immunologic Res. 317 (2013).

[18] Zakir Khan et al., *Slow CCL2-Dependent Translocation of Biopersistent Particles from Muscle to Brain*, 11 BMC Med. 1 (Apr. 2013).

to neurons." *Id.* Additionally, the study indicated that a person's tolerance for aluminum is variable. *Id.* He also cites *Gherardi et al.*,[19] a review article that contains no original data or research, as support for his claim that "[a]luminum and other poorly biodegradable materials taken up at the periphery by macrophages circulate in the lymphatic and blood circulation and can enter the brain causing impairment." *Id.*[20]

2. Respondent's Experts: Dr. Cetaruk and Dr. Whitton

Respondent filed reports from two experts—Dr. Edward W. Cetaruk (Resp. Ex. C) and Dr. Lindsay Whitton (Resp. Ex. A). Dr. Cetaruck graduated from New York University School of Medicine and is board certified in emergency medicine and medical toxicology. He completed a residency in emergency medicine, followed by a two year fellowship in medical toxicology. He is currently an Assistant Clinical Professor of Medicine at the University of Colorado Health Sciences Center. Resp. Ex. D. Dr. Whitton graduated from the University of Glasgow, Scotland where he received an M.D., in medicine and a Ph.D. in Immunology. He is currently a Professor of Immunology and Microbial Science at Scripps Research Institute. Resp. Ex. B.

Both experts criticized several of the studies relied upon by Dr. Dahlgren. With respect to *Santiago et al.*, both Dr. Cetaruk and Dr. Whitton stated that it lacked control groups and suffered from significant selection bias—all participants in the study had pre-existing diagnoses of autoimmune or inflammatory conditions. Resp. Ex. E at 20; Resp. Ex. A at 14. These criticisms are shared by the World Health Organization and were fully discussed at a 2002 workshop held by the National Vaccine Program Office of the Department of Health and Human Services. Resp. Ex. E at 18-20. *Luján et al.* was also criticized by both Dr. Cetaruk and Dr. Whitton as containing severe design flaws. Resp. Ex. E at 24-25; Resp. Ex. A at 15-16. In this study of "ovine ASIA," the experimental sheep were given the same schedule of full vaccinations rather than receiving only the vaccine adjuvant. *Id.* "As a result . . . whatever role the vaccinations adjuvants may have played in the development of the syndrome remains undefined." Resp. Ex. E at 25; *see* Resp. Ex. A at 17-18 ("[G]iven the experimental design, it simply is not possible to identify the responsible vaccine component (if any)."). Moreover, the study contained only two groups, a "striking error" that, according to respondent's experts, resulted in a failure to "provide sufficient controlled data essential to proving a causal association between an exposure and an effect." Resp. Ex. A at 16; Resp. Ex. E at 25. Dr. Whitton also noted that *Exley et al.*—which was published in a journal that describes its articles as positing "novel, radical new ideas and speculations in medicine" that "would be rejected by most conventional journals"[21]—suffered from a similar lack of control data. Resp. Ex. A at 20.

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[19] Romain Kroum Gherardi et al., *Biopersistence and Brain Translocation of Aluminum Adjuvants of Vaccines*, 6 Frontiers Neurology 1 (2015).

[20] Dr. Dahlgren cited other studies in his report; however, *none* of the referenced studies was filed along with the report. Some (but not all) of the articles referred to by Dr. Dahlgren were submitted by respondent's experts and were therefore reviewed by the undersigned, as discussed above.

[21] *Medical Hypotheses*, Elsevier: Journals, http://www.journals.elsevier.com/medical-hypotheses (last visited July 10, 2017).

Finally, the experts dispute the relevance of *Khan et al.*, a study that reports data from mice concerning the biodistribution of alum-particle fluorescent surrogates injected into mouse muscle. See Resp. Ex. E at 14; Resp. Ex. A at 19. Dr. Cetaruk asserts that this study "makes no conclusions and offers absolutely no data regarding the development of MMF or any other pathological condition after immunization with an aluminum adjuvant-containing vaccine." Resp. Ex. E at 14. Dr. Whitton also asserts that this study lacked controls, noting that the mice were fed "commercial grain based rodent diets," which, as the study itself admits, "contained substantially higher concentrations of aluminum than human diets." Resp. Ex. A at 19 (emphasis omitted).

In sum, respondent's experts concluded that "there is no persuasive or reliable evidence to support petitioner's claim that he suffered a vaccine-related injury as a result of his October 14" vaccine, Resp. Ex. A at 21, and that "Dr. Dahlgren's report does not provide a sufficient scientific basis to support his opinions nor does he offer sufficient medical literature to support a causal relationship between" petitioner's vaccination and any injury, Resp. Ex. E at 28.

D. Procedural History

Petitioner filed his petition on December 3, 2013, and filed his medical records (Pet. Exs. 3-15),[22] affidavit (Pet. Ex. 2), and a copy of his birth certificate (Pet. Ex. 1) two weeks later. ECF No. 5.

This case was first assigned to Chief Special Master Dorsey.[23] The initial status conference was conducted on February 11, 2014. Respondent was ordered to file a status report by March 13, 2014, indicating whether any medical records remained outstanding or provide a date to file a Rule 4(c) Report. Order, issued Feb. 12, 2014, ECF No. 7.

On March 11, 2014, respondent filed a status report (hereinafter "Resp. S.R."), identifying outstanding medical records. Resp. S.R., ECF No. 8. Petitioner was ordered to file the outstanding medical records by May 12, 2014. Scheduling Order, ECF No. 9.

On May 12, 2014, petitioner filed a motion for an extension of time to file additional records, which was granted. ECF Nos. 10-11. On July 11, 2014, petitioner filed updated medical records (Pet. Exs. 16-20)[24] and a status report (hereinafter "Pet. S.R."), advising that he

[22] Express Care Plus (Pet. Ex. 3); Centura Health St. Francis Medical Center (Pet. Ex. 4); Colorado Springs Orthopedic Group (Pet. Ex. 5); Movement & NeuroPerformance Center (Pet. Ex. 6); Dr. Rubick Causation letter (Pet. Ex. 7); Musolf Chiropractic Center (Pet. Ex. 8); North Springs Family Medicine (Pet. Ex. 9); Memorial Hospital (Pet. Ex. 10); Orthopedic Rehab Association (Pet. Ex. 11); Orthopedic Rehab Associations – Past Medical (Pet. Ex. 12); Musolf Chiropractic Clinic – Past Medical (Pet. Ex. 13); Express Care Plus – Past Medical (Pet. Ex. 14); North Springs Family Medicine – Past Medical (Pet. Ex. 15).

[23] This case was reassigned to me on October 21, 2015. ECF No. 32.

[24] Express Care Plus Updated Records (Pet. Ex. 16); Movement & Neuroperformance Center Updated Records (Pet. Ex. 17); Musolf Chiropractic Updated Records (Pet. Ex. 18); Orthopedic Rehab Associates Updated Records (Pet. Ex. 19); Urological Associates Updated Records (Pet. Ex. 20).

was awaiting records from one additional provider, as well as laboratory reports. Pet. S.R., ECF No. 13. Petitioner was ordered to file the outstanding records and a statement of completion by August 25, 2014. Respondent was to file a status report indicating whether the parties wished to engage in settlement discussions thirty days thereafter. Order, issued Jul. 11, 2014, ECF No. 14.

Petitioner filed additional medical records (Pet. Exs. 21-22) and a statement of completion on August 20, 2014. ECF Nos. 17-18. On September 19, 2014, respondent filed a status report advising that respondent did not believe this matter was appropriate for settlement. Resp. S. R., ECF No. 19. Respondent was ordered to file a Rule 4 Report by October 24, 2014. Order, issued Sept. 22, 2014, ECF No. 20.

Respondent filed a Rule 4 Report on October 24, 2014, stating that, based "[o]n the existing record, petitioner ha[d] not established preponderant evidence in support of the petition for compensation, and compensation under the Act for his alleged injuries must be denied." Resp. Rule 4 Report, ECF No. 22 at 16.

A Rule 5 conference was held on November 20, 2014. The parties were encouraged to discuss a possible informal resolution of this claim. Petitioner was ordered to send a settlement demand to respondent and to file a status report confirming that a demand was sent by January 6, 2015. Respondent was to file a status report updating the Court on the parties' settlement discussions forty-five days thereafter. Order, issued Nov. 20, 2014, ECF No. 23.

On January 6, 2015, petitioner filed a status report indicating that an initial demand had been emailed to respondent. Pet. S.R., ECF No. 24. Respondent filed a status report on February 19, 2015, stating that respondent had done a preliminary review of the record and was revisiting this case for possible settlement in light of petitioner's settlement demand. Resp. S.R., ECF No. 25. Respondent was ordered to file a joint status report by March 23, 2015, advising the Court on the status of the parties' settlement discussions. Order, issued Feb. 19, 2015, ECF No. 26.

On March 23, 2015, respondent filed a status report advising that respondent had decided to defend the case for the reasons set forth in the Rule 4 report. Resp. S.R., ECF No. 27.

A status conference was held on June 9, 2015. During the conference, petitioner's counsel stated that Mr. Mitchell recently saw a neurologist, and those records would be filed when available. Petitioner was ordered to file his most recent medical records and an expert report by August 10, 2015. Respondent's expert report was due sixty days thereafter. Order, issued June 9, 2015, ECF No. 28.

On August 7, 2015, petitioner filed additional records and an expert report from Dr. Dahlgren. Pet. Exs. 23-29, ECF No. 29. On November 18, 2015, respondent filed expert reports from Dr. Whitton and Dr. Cetaruk. Resp. Exs. A-D, ECF Nos. 35-36. Five days later, respondent filed a supplemental expert report from Dr. Cetaruk. Resp. Ex. E, ECF No. 37.

A status conference was held on February 5, 2016. During the conference, the parties discussed the possibility of informally resolving this matter. Respondent's counsel was ordered

to file a status report indicating how respondent would like to proceed. Order, issued Feb. 5, 2016, ECF No. 38. On March 25, 2016, respondent filed a status report stating that respondent wanted to defend this matter. Resp. S.R., ECF No. 40.

A status conference was held on April 19, 2016. During the conference, petitioner's expert report was discussed, particularly the concern that petitioner's expert relied solely on the ASIA theory. It was pointed out that the Federal Circuit had recently upheld a decision rejecting the ASIA theory as essentially underdeveloped. *See D'Angiolini v. Sec'y of Health & Human Servs*., 645 F. App'x 1002 (Fed. Cir. 2016), *aff'g* 122 Fed. Cl. 86 (2015). Petitioner's counsel was directed to read *D'Angiolini* before spending additional money on a supplemental expert report. The undersigned also noted that, in addition to petitioner's expert's reliance on the ASIA theory, petitioner had not been diagnosed with an autoimmune disease or been given any other definitive diagnosis. Petitioner was ordered to file a status report stating how he intended to proceed by May 19, 2016. Order, issued April 19, 2016, ECF No. 41.

On May 10, 2016, petitioner's counsel filed a Motion for Interim Attorneys' Fees and Costs in which he stated he intended to withdraw as counsel (hereinafter "Motion for Interim Fees"). ECF No. 43. A week later, petitioner filed a Motion for a Ruling on the Record (hereinafter "Motion on Record"), stating that he had submitted all the evidence he intended to file in this matter. ECF No. 45. On May 27, 2016, respondent filed a response to petitioner's Motion for Interim Fees, "urg[ing] the Special Master to deny petitioner's request for attorneys' fees and costs until such time as the case ha[d] concluded, or upon determination that an award for interim fees [was] appropriate, as set forth in *Avera v. Sec'y of Health & Human Servs.*, 515 F.3d 1342 (Fed. Cir. 2008)." Respondent did not object to the overall amount sought. *See* Response to Interim Fees, ECF No. 46. Given petitioner's request for a Ruling on the Record, the issue of fees has not yet been addressed.

On June 6, 2016, respondent filed a response to petitioner's Motion for a Ruling on the Record. Respondent stated that—based on the existing record, which includes the medical records and expert reports filed by the parties—entitlement to compensation must be denied and the petition dismissed. *See* Response to Ruling on Record, ECF No. 47. Thereafter, respondent filed over 50 exhibits of medical literature. Resp. Exs. F-L, ECF Nos. 48-54.

A status conference was held on December 20, 2016. The undersigned discussed the various issues in this case, including the timing of petitioner's complaints, many of which pre-dated the allegedly causal vaccination; petitioner's lack of a definitive diagnosis; petitioner's reliance on the rejected ASIA theory of causation; and petitioner's failure to file any medical literature in support of his expert's opinion. The parties were advised that the record does not support a finding of entitlement for compensation. Petitioner's counsel was ordered to file a status report by February 3, 2017, indicating how petitioner intended to proceed. Order, issued Dec. 20, 2016, ECF No. 55.

On January 11, 2017, petitioner filed a status report stating that he would like to move forward with his previously filed Motion for a Ruling on the Record. Petitioner's report included an affidavit waiving his right to a hearing and indicating his understanding that his medical history may become public. Pet. S.R., ECF No. 56. This matter is now ripe for decision.

II. Legal Framework

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that he suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii). An "off-Table" claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii)(II). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In addition, the Vaccine Act requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted for more than six months. § 11(c)(1)(D)(i).

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Id*. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948). Only where later testimony is "consistent, clear, cogent and compelling" can it "overcome the presumption of accuracy afforded to contemporaneous medical records." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (quoting *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrel Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010). The *Daubert* 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"). 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). And 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 ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Finally, although this decision discusses some but not all of the literature in detail, the undersigned reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

III. Analysis

Because petitioner does not allege an injury listed on the Vaccine Injury Table, petitioner's claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, petitioner must prove by preponderant evidence that he suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. Injury Requirement

The first step in an "off-Table" claim is to "determine what injury, if any, was supported by the evidence presented in the record." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). The Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury," and "[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached." *Id.*; *see Broekelschen*, 618 F.3d at 1346 (explaining that "identifying the injury is a prerequisite to the [causation] analysis").

The petition in this case does not allege that petitioner was diagnosed with any definitive injury following the allegedly causal vaccination. Rather, petitioner alleges that he suffers from several "medical issues" including "myositis, vertigo, nausea, muscle aches, spasms, and dizziness, as well as neck, lumbar back and left knee problems and swelling." Pet. at 2. These symptoms do not constitute a "defined and recognized injury." *Lombardi*, 656 F.3d at 1353; *see also Lasnetski v. Sec'y of Health & Human Servs.*, 128 Fed. Cl. 242, 261-62 (2016) (finding that the petitioner bears the burden to show by preponderant evidence a medically-recognized injury, not "mere descriptions of symptoms" of an unknown injury). Most of the alleged "medical issues" predate the vaccination. *See* Pet. Ex. 13 (noting that between 2009 and 2012, petitioner

sought treatment more than 80 times for complaints of severe muscle spasms, neck and back pain, numbness, and tingling). And petitioner's complaints of dizziness and vertigo symptoms first appear in the medical records in January 9, 2013—more than three months after his vaccination.

Moreover, petitioner's records do not show that any physician diagnosed him with having myositis. Instead, they reveal only a history of petitioner using the term "myositis" when seeking medical treatment. *See, e.g.*, Pet. Ex. 5 at 9 ("[Petitioner] feels it may be related to polymyositis which may have occurred after a DTAP vaccination reaction."); Pet. Ex. 11 at 1 ("[Petitioner] reports that the TDaP vaccine caused him to have myositis, which he reports is an autoimmune disease process."). Petitioner's expert also appears to erroneously equate petitioner's self-diagnosis of myositis with an actual diagnosis. *Compare, e.g.*, Pet. Ex. 28 at 4 (declaring that Dr. Giroux's "diagnosis was myositis"), *with* Pet. Ex. 6 at 1 (noting that petitioner claimed he suffered from "myositis" but finding "[m]uscle spasm, imbalance, loss of stamina of unclear etiology").

Finally, Dr. Dahlgren concludes that petitioner has a "vaccination induced autoimmune disease." Pet. Ex. 28 at 7. However, none of petitioner's contemporaneous medical records contain any diagnosis of an autoimmune disease or evidence that an autoimmune process was occurring, such as proof of inflammation. *See Lombardi*, 656 F.3d at 1353 (noting the "special value that we have placed on the opinions of treating physicians"); *cf.* Pet. Ex. 4 at 38 (petitioner's bloodwork on November 1, 2012, contains no elevation of inflammatory markers). Dr. Dahlgren's expert report is the only documentation concluding that petitioner has an autoimmune disease, a conclusion that is not supported with any objective testing, lab results, or medical records. However, Dr. Dahlgren is not a neurologist, rheumatologist, or immunologist, and is thus not qualified to make such a diagnosis without some supportive testing. *See, e.g.*, *Veryzer v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 214, 224 (2011) (finding the special master properly rejected petitioner's expert on the reasonable ground that she lacked the requisite expertise in neurology, which was the subject of her testimony); *Gardner-Cook v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 38, 46, 49 (2003) (finding that special master properly found that expert was not qualified to testify that petitioner suffered from a demyelinating disease when he had never practiced neurology or neuroimmunology). Dr. Dahlgren apparently recognized this limitation when he suggested that petitioner see a rheumatologist for testing, which petitioner failed to do. Pet. Ex. 28 at 5. Nevertheless, Dr. Dahlgren "diagnosed" petitioner with an "autoimmune disease" based on a telephone conversation with petitioner and on petitioner's medical records—records that, according to Dr. Dahlgren, contained a "striking . . . lack of detail." Pet. Ex. 28 at 4, 7.

Because petitioner had never been diagnosed with an autoimmune disease by his treating physicians, or shown he was otherwise suffering from such an illness, petitioner has failed to establish by preponderant evidence that he has an autoimmune disease; that claim appears to have "originated in this litigation." *Lombardi*, 656 F.3d at 1353-54 (citation omitted) (upholding special master's determination that the petitioner did not suffer from transverse myelitis where the "treating physicians . . . did not diagnose transverse myelitis" and medical testing did not support such a diagnosis by the expert).

B. Causation Requirement (*Althen* Analysis)

"In the absence of a showing of the very existence of any specific injury of which petitioner complains, the question of causation is not reached." *Id.* at 1353. But even if petitioner had shown some definable injury, petitioner has failed to prove causation under the three-pronged test established in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Petitioner fails on all three prongs.

1. Reputable Medical Theory

The first *Althen* prong requires petitioner to provide a "reputable medical theory" demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994)). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014). Petitioner has not offered a plausible theory of causation in this case.

As noted above, Dr. Dahlgren opines that vaccinations containing aluminum adjuvants can have some adverse effect on the immune system. Pet. Ex. 28 at 7. Dr. Dahlgren then concludes that petitioner "probably" has "Macrophagic Myofasciitis (MMF)," a purported "subset" of ASIA. *Id.*

The validity of the ASIA theory has been repeatedly called into doubt by other special masters. *See D'Angiolini v. Sec'y of Health & Human Servs.*, 122 Fed. Cl. 86, 102 (2015) (upholding special master's "determin[ation] that ASIA does not provide[] a biologically plausible theory for recovery"), *aff'd*, 645 F. App'x 1002 (Fed. Cir. 2016); *Garner v. Sec'y of Health & Human Servs.*, No. 15-063V, 2017 WL 1713184, at *8 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (observing that the ASIA theory "is, at a minimum, incomplete and preliminary—and therefore unreliable from an evidentiary standpoint"); *Johnson v. Sec'y of Health & Human Servs.*, No. 10-578V, 2016 WL 4917548, at *7-9 (Fed. Cl. Spec. Mstr. Aug. 18, 2016) (rejecting Dr. Shoenfeld's expansive medical theory that "any adjuvant [is] capable of causing any autoimmune disease," finding it "overbroad, generalized, and vague, to the point that it could apply to virtually everyone in the world who received a vaccine containing an adjuvant and then at some time in their lives developed an autoimmune disease"); *Rowan v. Sec'y of Health &*

Human Servs., No. 10-272V, 2014 WL 7465661, at *12 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) (rejecting the ASIA theory because it "is not a proven theory" and no "persuasive or reliable evidence" supports it). The primary reason for ASIA's rejection is its "changing and imprecise" diagnostic criteria, which are unable to "distinguish between afflicted and un-afflicted patients." *D'Angiolini*, 122 Fed. Cl. at 102. The "major" criteria include "dry mouth," "arthralgia" (simple joint pain), and "myalgia" (simple muscle pain); the "minor" criteria include "[o]ther clinical manifestations" and "autoimmune disease." *Id.*; *see* Resp. Ex. E at 16-17. Exacerbating the expansiveness of these criteria, only "two major or one major and two minor criteria" are necessary for diagnosis. *D'Angiolini*, 2014 WL 1678145, at *58. This does very little to "separate people with the disease from people without the disease." *Id.* at *59.

These flaws remained unaddressed by Dr. Dahlgren. His expert report does not elaborate on the ASIA theory, provide any further scientific proof of the ASIA theory, or add any additional evidence to support the ASIA theory. It simply repeats what has already been rejected in the cases cited above. Petitioner has failed to provide a reputable medical theory and therefore failed to satisfy his burden under *Althen*'s first prong.

2. Logical Sequence of Cause and Effect

Although petitioner's failure to satisfy the first prong of *Althen* renders further analysis unnecessary, *see de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1350 (Fed. Cir. 2008), the remaining factors will nonetheless be addressed. The second *Althen* prong requires proof of "[a] logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccination can cause the injury alleged, petitioner must show "that it did so in [his] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "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," *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

Petitioner fails on this prong as well. As the medical records establish, petitioner was not diagnosed with an autoimmune disease from the vaccination he received. Dr. Dahlgren concludes that petitioner has an autoimmune disease without any basis in lab testing. Dr. Dahlgren either fails to consider or simply disregards the bloodwork taken on November 1, 2012, in the Emergency room that was normal with no inflammatory markers. *See* Pet. Ex. 4 at 38. Instead, after stating that "[i]n some susceptible people the aluminum over-stimulates the immune[] system and causes the immune system to attack the person," Dr. Dahlgren declares, with no medical support, that petitioner "is one [of] those unfortunate people." Pet. Ex. 28 at 8. This conclusion amounts to "*ipse dixit* of the expert" and is insufficient to sustain petitioner's burden. *Snyder*, 88 Fed. Cl. at 743 (citation omitted).

Moreover, none of petitioner's treating physicians related his symptoms to the vaccination he received when he was being treated. Rather, it was *petitioner* who insisted (at several of his medical appointments) that the vaccination played a role in the symptoms he was

experiencing. *See, e.g.*, Pet. Ex. 11 at 1 (petitioner reported "[v]ertigo and imbalance dating back to October 2012 where he reports his health completely changed after having a TDaP injection"); Pet. Ex. 9 at 14 (petitioner reported "[h]e developed generalized muscle aches and spasm after Tdap injection"). And the letters relating petitioner's symptoms to the vaccination were written at petitioner's behest, several months after he received the vaccination and in preparation for this litigation. *See* Pet. Ex. 3 at 36 ("I have an opportunity for partial reimbursement from a court in Washington DC to recover some costs. It is not a lawsuit, it is a vaccination claims center. I need your professional opinion that the vaccination I received caused an auto-immune response, which allowed the myositis to enter and create havoc within my body."); Pet. Ex. 9 at 3 (letter from Dr. Rubick noting that "[Petitioner] requests my opinion in regards to this causal relationship, for there is apparently the ability for partial reimbursement for medical expenses if the association is made between this immunization and the onset of his symptoms.").

Dr. Rubick's April 27, 2013, letter states that, "in [his] opinion," it was "reasonable that [petitioner's] myalgia complaints were related to his TDaP immunization." Pet. Ex. 7 at 1. But that conclusion was not drawn by Dr. Rubick at the time petitioner was being treated. To the contrary, less than a month after petitioner received the vaccination, Dr. Rubick noted that petitioner's testing "ha[d] been negative" and that "his physical symptoms continue[d] to improve." Pet. Ex. 9 at 12. The same goes for Dr. Walton, who noted that, by petitioner's "own admission, the symptoms ha[d] subsided dramatically" on November 7, 2012 "without any further intervention." Pet. Ex. 3 at 18. Neither diagnosed petitioner with a vaccine-related injury or equated his complaints to any vaccination at the time of his visits. *See Gerami v. Sec'y of Health & Human Servs.*, 127 Fed. Cl. 299, 303, 306 (2014) (upholding special master's determination that "contemporaneously documented medical evidence" was "more persuasive than the letter prepared for litigation purposes").

In sum, petitioner has failed to prove by preponderant evidence that the vaccination he received did in fact cause any injury.

3. Proximate Temporal Relationship

To satisfy the third *Althen* prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

As petitioner acknowledges, his medical records show that his complaints of back pain, neck pain, and neck and back spasms actually began long before he received the vaccination.

See Pet. at 1 (acknowledging that "prior to receiving" the vaccine, he suffered from "soft tissue injuries to his neck, back and shoulders from a motor vehicle accident, hypertension, high cholesterol and arthritis"); Pet. Ex. 13 at 9-45 (cataloging petitioner's routine visits to his chiropractor, which began in early 2009, where he complained of knee pain, back spasms, and neck spasms). In the 45 days just before receiving the vaccination, petitioner presented to his chiropractor three times complaining of left knee pain and neck and back spasms. Pet. Ex. 13 at 44-45. In September of 2012, petitioner presented to Dr. Rubick complaining of knee pain as well as "other malaise and fatigue." Pet. Ex. 9 at 15; Pet. Ex. 15 at 1-2. Petitioner's medical records do not support a proximate temporal relationship between his receipt of the vaccination and the onset of any new symptoms that had not already complained of prior to the date of vaccination.

Furthermore, petitioner's complaints of dizziness did not begin until January 9, 2013—nearly three months after he received the allegedly causal vaccination. *Compare* Pet. Ex. 3 at 15 (petitioner reporting on October 31, 2012 that he was not experiencing any dizziness, headaches, or head pain), *with id.* at 20 (petitioner reporting on January 9, 2013 that he was experiencing dizziness).

Petitioner has therefore failed to prove by preponderant evidence a proximate temporal relationship between the vaccination and any alleged injuries.

IV. Conclusion

Upon careful evaluation of all of the evidence submitted in this matter—including the medical records, tests, and reports, as well as the experts' opinions and medical literature—the undersigned concludes that petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. Petitioner has failed to offer evidence showing that he suffered an identifiable injury, and he has failed to show that the vaccination he received caused any of any of his complaints. **His petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master