In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-285V
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SHAWN ORGEL-OLSON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Tetanus/Diphtheria (Td) vaccine; Hepatitis A vaccine; Sweet's syndrome; Serum sickness

Renee J. Gentry, Vaccine Injury Clinic, Georgetown University Law School, Washington, DC, for petitioner.
Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On March 19, 2015, petitioner, Shawn Orgel-Olson, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10-34 (2012),[2] alleging that he suffered "neurological injuries" as a result of his August 3, 2012 Tetanus/Diphtheria (Td) and Hepatitis A vaccination.[3] In advance of the hearing, petitioner narrowed his focus, specifically arguing that his correct diagnoses are Sweet's syndrome and serum

[1] When this decision was originally filed the undersigned advised his intent to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner filed a timely motion to redact certain information. This decision is being reissued with two redactions within petitioner's prior medical history marked as "[. . .]" and omitting disclosure of a certain aspect of two of petitioner's prior medical encounters that are not germane to the analysis contained in this decision. Except for those changes and this footnote, no other substantive changes have been made. This decision will be posted on the court's website with no further opportunity to move for redaction.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

[3] The petition included an extensive recitation of petitioner's medical records inclusive of multiple different diagnoses considered by his treating physicians but was otherwise no more specific in his allegations than to state that the vaccines at issue caused "neurological injuries." (ECF No. 1, pp. 1, 32-33.)

sickness. (ECF No. 102, p. 11.) For the reasons set forth below, I conclude that petitioner is not entitled to an award of compensation for this injury.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury not of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based

solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting their claim, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program fact finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

In this case, petitioner alleges that he suffered Sweet's syndrome, a serum sickness like reaction, and/or neurologic injuries, as a result of his Td and Hepatitis A vaccinations. (ECF No. 102.) Because these injuries are not listed as Table Injuries, petitioner must satisfy the above-described *Althen* test for establishing causation in fact. *See* 42 C.F.R. § 100.3(a).

II. Procedural History

Mr. Orgel-Olson filed his petition on March 19, 2015. (ECF No. 1.) This case was initially assigned to Special Master Laura Millman. (ECF No. 4.) On March 24, 2015, petitioner filed his vaccination record, VAERS report, and medical records from a number of providers.[4] (ECF Nos. 5, 6.) On May 14, 2015, petitioner filed two affidavits and additional medical records from Stanford Hospitals & Clinics, Paolo Alto Medical Foundation, Dignity Health Medical Group, University of California-San Francisco Medical Center, and Dermatology Surgical & Medical Group. (ECF Nos. 11, 12, 13.)

Respondent filed his Rule 4 Report recommending against compensation on July 9, 2015. (ECF No. 17.) The following day, petitioner filed medical records from dentists Christopher Kurimoto and Jerel Philip, disability records from the California Employment Development Department, and additional medical records from the University of

[4] Specifically, Dignity Health Medical Group, Scripps Memorial Hospital, the University of California-Berkley, Barton Memorial Hospital, Verdugo Hills Medical Associates, Neurologist Dr. Joydip Bhattacharya, Allergy & Asthma Associates, UCLA Healthcare, Pacific Center for Integral Health, Stanford Hospitals & Clinics, Rheumatologist Dr. Lester Miller, Massachusetts General Hospital, Five Branches Acupuncture Clinic, Licensed Acupuncturist Holly Guzman, and Wellspring Therapy.

California-San Francisco Medical Center on July 10, 2015. (ECF No. 18). On March 25, 2016, petitioner filed a letter from his treating physician, Dr. Safwan Jaradeh. (ECF No. 28.) Dr. Jaradeh, a neurologist at the Stanford neuro-autonomic clinic, characterized petitioner's condition as serum sickness leading to autonomic neuropathy. (Ex. 30, p. 2.) Respondent filed an expert report by neurologist Phillip Low, M.D., and the accompanying medical literature on June 10, 2016. (ECF No. 31.) Petitioner then filed updated medical records from Dignity Health on June 29, 2016. (ECF No. 33.)

On March 24, 2017, petitioner's current counsel of record was substituted as counsel in this case. (ECF No. 52.) Thereafter, petitioner raised no further argument based on Dr. Jaradeh's opinion. (ECF Nos. 100, 102, 104.) Instead, on January 24, 2018, petitioner filed an expert report from neurologist Carlo Tornatore, M.D. (ECF No. 60.) The medical literature accompanying Dr. Tornatore's report was filed on February 9, 2018. (ECF Nos. 63, 64, 65.) Dr. Tornatore endorsed serum sickness and Sweet's syndrome as explanations for petitioner's condition. (Ex. 32, p. 5.) On June 11, 2018, respondent filed an expert report and the accompanying medical literature from dermatologist Michael Girard, M.D. (ECF No. 68.) Respondent also filed a supplemental report by Dr. Low on June 15, 2018. (ECF No. 70.)

This case was subsequently reassigned to my docket on June 6, 2019. (ECF No. 74.) Petitioner filed additional medical records from Dominican Medical Group on October 2, 2019. (ECF No. 82.) Respondent then filed an expert report from immunologist You-Wen He, M.D., on October 7, 2019. (ECF No. 84.) I initially scheduled a two-day entitlement hearing for May 19, 2020. (ECF No. 81.) However, due to the Covid pandemic, the hearing was bifurcated, with the original hearing held as a one-day video fact hearing to commence on May 19, 2020, and a separate entitlement hearing to commence the following year when it was anticipated that expert testimony could be taken in person. (ECF No. 89.)

The video fact hearing was conducted, as scheduled, on May 19, 2020. (*See* ECF No. 94 (Transcript of Proceedings ("Tr.")), 5/19/2020.) Petitioner was the only witness to testify. During the fact hearing, several additional pieces of evidence were identified. On May 20, 2020, petitioner filed photographs of the skin condition he alleged was caused by his vaccine. (ECF No. 91.) On May 26, 2020, petitioner also filed two videos of fasciculations[5] in his arm and leg that he alleges were caused by the vaccine. (Ex. 53.) On June 21, 2020, petitioner filed a chronology of his symptoms he had previously created for his doctors. (ECF No. 95.) The parties were permitted an opportunity to have their experts review the fact hearing testimony and subsequently produced evidence; however, on August 11, 2020, petitioner filed a joint status report on behalf of the parties indicating that they did not believe any additional expert reports were necessary to develop the record. (ECF No. 97.)

[5] A Fasciculation is a "small local contraction of muscles, visible through the skin, representing a spontaneous discharge of a number of fibers innervated by a single motor nerve filament." *Fasciculation*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=18204 (last visited March 2, 2022).

Expert testimony was ultimately heard in a two-day entitlement hearing in this case commencing April 22 and continuing on April 30, 2021. (*See* ECF No. 110 (Transcript of Proceedings ("Tr.")), 4/22/2021, and ECF No. 112 (Transcript of Proceedings ("Tr.")), 4/30/2021.)[6] Due to the ongoing pandemic, expert testimony was heard by video rather than in person as originally anticipated. Drs. Tornatore and He testified on April 22 and Dr. Low testified on April 30. Respondent did not call upon Dr. Girardi to testify. At the close of the hearing on April 30, both parties confirmed that the record of this case is closed. (Tr. 243.) Accordingly, this case is now ripe for a decision.

III. Factual History

a. As Reflected in Petitioner's Medical Records

Prior to his August 3, 2012 vaccination, petitioner was a relatively healthy, 25-year-old man. Petitioner previously received polio, tetanus, MMR, and varicella vaccinations as a child. (Ex. 1, p. 2-6.) Petitioner was seen by University Health Services at the University of California, Berkeley on November 5, 2009, for flu-like symptoms including myalgias, headache, and transient rashes on his hands lasting several weeks. (Ex. 4, pp. 8-10.) Additionally, Dr. Dean Kashino saw petitioner on December 12, 2011, for a left knee injury and [. . .]. (Ex. 2, p. 279.) The parties agree that petitioner's pre-vaccination history is noncontributory to his alleged vaccine-related injury. (ECF No. 100, p. 2.) In preparation for a trip to Cambodia, petitioner received the Td and Hepatitis A vaccinations at issue in this case from Dr. Kashino on August 3, 2012. (Ex. 2, p. 266-67.)

Just over two weeks later, on August 20, 2012, petitioner called Dr. Kashino and reported that he was experiencing dizziness, neck pain, soreness for the past several days, and that his head had felt swollen for about a week. (*Id.* at 271.) Petitioner denied fever, chills, nausea, and abdominal pain. (*Id.*) Later that day, petitioner reported to Verdugo Hills Medical Associates emergency department complaining of head pressure, neck pain, and dizziness for one week. (Ex. 6, p. 2-3.) Petitioner's exam was normal apart from mild pharyngeal erythema and congestion of the right maxillary sinus. (*Id.* at 2.) Petitioner was prescribed Zithromax (azithromycin) for a possible sinus infection.[7] (*Id.* at 2-3.)

[6] All three hearing transcripts (ECF Nos. 94, 110, and 112) are continuously paginated and are cited collectively throughout this decision as "Tr."

[7] The medical records need to be examined closely to answer the question of whether petitioner ever actually took the prescribed azithromycin. On August 28, 2012, Dr. Kashino documented that petitioner had not yet had the prescription filled (referencing it as a "Zpack"). (Ex. 2, p. 270.) Later, on August 30, 2012, Dr. Kashino recorded that petitioner declined to take the azithromycin because he doubted the sinusitis diagnosis. (*Id.* at 268.) Subsequently, however, petitioner reported to a different physician (Dr. Bhattacharya) on September 4, 2012. (Ex. 7, pp. 14-15.) At that time, Dr. Bhattacharya elicited a history in which petitioner reported that he had started taking azithromycin four days prior – this would mean he started taking the medication on about August 31, one day subsequent to his August 30 encounter with Dr. Kashino – and subsequently felt "much better." (*Id.* at 15.) A later appointment with a third physician

On August 28, 2012, petitioner again called Dr. Kashino, this time reporting mild headaches and sinus congestion for two weeks and questioning whether his symptoms were vaccine related. (Ex. 2, p. 270.) Petitioner denied that he was experiencing any fever or rash and Dr. Kashino noted that petitioner's condition "sounds viral" and that a "reaction to Hep A vaccine" was "less likely." (*Id.*) Petitioner returned to Dr. Kashino on August 30, 2012. (*Id.* at 268.) He explained that he experienced soreness in his neck, pressure in his temples, and lightheadedness about five days after his recent vaccinations. (Ex. 2, p. 268.) Petitioner noted that his sinus and headache issues were slow to improve, and that he was experiencing jaw pain and increasing pressure in his head for a week. (*Id*.) Petitioner reported pain at the injection site, but was negative for fever, myalgia, or arthralgia. (*Id*.) Dr. Kashino felt that petitioner's symptoms were "very vague" and believed that petitioner's jaw pain was the result of TMJ Syndrome and ordered a general blood workup to check for signs of infection, inflammation, and other potential explanations of petitioner's fatigue. (*Id.* at 269.) Nonetheless, a VAERS report was completed. (*Id.* at 263.) It documented fatigue as well as pain in petitioner's jaw, temple, and cervical spine. It included no reference to rashes, lesions, or fever. (*Id.*) Dr. Kashino later interpreted the lab results as demonstrating "no significant abnormalities." (*Id.* at 126.)

Petitioner was seen by Dr. Joydip Bhattacharya for a neurological consultation on September 4, 2012. (Ex. 7, p. 14.) He reported onset of head and neck pain and pressure occurring about one-week post-vaccination and without fever. Petitioner did not describe any new symptoms and had an unremarkable physical exam; however, he was feeling much better after starting azithromycin. (*Id.* at 15-17.) Dr. Bhattacharya assessed petitioner with "[p]ossible aseptic meningitis VS unusual vaccination reaction," but declined to conduct a lumbar puncture because petitioner was "doing [well] and on the way to recovery." (*Id.* at 18.) Dr. Bhattacharya indicated he would do a spinal tap if petitioner's recovery stalled. (*Id*.)

On September 7, 2012, petitioner called Dr. Kashino to explain that his jaw pain and left-temporal headache had resolved. (Ex. 2, p. 265.) He reported, however, that he was still fatigued, feeling tenderness in his right temple, and was now suffering transient rashes and noticing pain in his joints and the fat pads of both hands. (*Id.* at 54, 261-62, 264.) On September 11, 2012, Dr. Kashino called petitioner to follow up on his symptoms. (Ex. 2, p. 264.) During this call, petitioner explained that he was also

(Dr. Kaufmann) on September 14, 2012, again confirmed that petitioner had taken the azithromycin ("z pack"). (Ex. 2, p. 261.) A later record by Dr. Kashino from a visit occurring October 19, 2012, again indicates that petitioner did not take the prescribed azithromycin; however, it appears that Dr. Kashino copied over a large portion of the relevant paragraph from his prior August 30 history of present illness into this later record. (*Compare* Ex. 2, p. 253, *and* 268.) At subsequent appointments in December of 2012 petitioner again confirmed to physicians that he started taking the azithromycin on August 31 and that he felt it helped. (Ex. 2, p. 230; Ex. 13, p. 7.) Thus, notwithstanding petitioner's testimony that he only took Flonase and Claritin following his urgent care appointment (Tr. 15), the contemporaneous medical records preponderantly indicate otherwise. Based on my review of the record as a whole, I conclude that petitioner did take a course of azithromycin beginning August 31, 2012, and that it did alleviate at least some of petitioner's pain symptoms.

beginning to experience arthralgias in his legs. (*Id.*) Petitioner was worried about Lyme Disease and West Nile Virus because he had gone on a ten-mile hike about two weeks prior to onset of his illness. (*Id.*) Dr. Kashino suggested petitioner see an infectious disease specialist. (*Id*.)

Petitioner was seen by infectious disease physician Dr. John Kaufmann on September 14, 2012. (Ex. 2, p. 261.) Dr. Kaufman noted a normal physical exam, and recorded symptoms of needle-like joint pain that was worse in the hands, rashes on arms and hands, abdominal pain in the right lower belly, anxiety due to worsening symptoms, [. . .], fatigue, headache with cervical soreness and bilateral jaw pain, and a knee sprain. (*Id.*) Dr. Kaufmann noted that petitioner's reported arthralgia did not arise until later, after petitioner had taken the prescribed "z-pack." (*Id*.) Dr. Kaufmann felt it was difficult to find a unifying infectious diagnosis to explain petitioner's symptoms. (*Id.* at 262.) Dr. Kaufmann believed that petitioner's symptoms would resolve with time and noted that considering petitioner's normal initial test results, the next step would involve invasive testing, such as lumbar punctures or liver and bone marrow biopsies, which Dr. Kaufmann emphatically recommended against unless petitioner continued to report severe symptoms. (*Id.*) Dr. Kaufmann included "adverse effect of vaccines" among his assessments but specified that it was "per patient perception." (*Id.*)

Petitioner returned to Dr. Bhattacharya on September 17, 2012, for a follow-up. (Ex. 7, p. 7.) Dr. Bhattacharya noted that, in addition to his hands and wrist, petitioner was also developing joint pain in his leg, feet, and shoulders. (*Id.* at 8.) He also observed "some small pruritic reddish lesions" on examination. (*Id*. at 10.) Dr. Bhattacharya suggested petitioner had experienced an "[e]pisode of symptoms suggestive of aseptic meningitis following a tetanus shot and Hepatitis A immunization, now with polyarticular arthritic symptoms." (Ex. 7, p.10.) He noted that his symptoms are suggestive of an inflammatory polyarthropathy, but stressed that lab results had been negative. Dr. Bhattacharya felt a referral to rheumatology was appropriate, as he felt suspicion of a primary neurological illness was low, and indicated she would not pursue any spinal tap unless Dr. Kaufmann (infectious disease) felt it was indicated. (*Id*.)

Petitioner then went back to Dr. Kaufmann for a follow up exam on September 21, 2012. (*Id.* at 259.) He reiterated his concern that he might have been exposed to something while hiking in southern California. (*Id*.) Petitioner's physical exam was normal, his labs were unremarkable, he was negative for Lyme disease, and his total protein showed mild elevation. (*Id.* at 260.) Dr. Kaufmann reiterated that it is "difficult" to establish a unifying diagnosis for petitioner's entire illness. (Ex. 2, p. 260.) Dr. Kaufmann believed that the time course of petitioner's symptoms ruled out any occult infection but prescribed Ativan as well as doxycycline as a "desperate last resort" and based on petitioner's "strong enthusiasm," its anti-inflammatory properties, and the remote possibility that petitioner may have contracted Lyme disease or some other rickettsial infection. (*Id.* at 260.)

On September 26, 2012, Dr. Kaufmann cleared petitioner to return to work. (*Id.* at 256.) However, petitioner called Dr. Kashino on this day to describe new symptoms of tightening throat muscles that had lasted for several weeks. (*Id.* at 257.) Dr. Kashino prescribed ranitidine and suggested an ear, nose, throat specialist if petitioner did not improve. (*Id.*) Petitioner was next seen by Dr. Kashino on October 19, 2012. (*Id.* at 253.) Petitioner's physical exam was normal, but Dr. Kashino noted that petitioner continued to suffer from headaches, neck pain, jaw pain, dilated veins, and pressure over his temporal parietal areas bilaterally. (*Id.*) Dr. Kashino was still unable to diagnose petitioner's condition and indicated that he would seek authorization for a brain MRI. (*Id.* at 254.) Petitioner had stopped taking doxycycline after 16 days. (*Id.* at 253.)

On October 29, 2012, petitioner's mother called Dr. Kashino indicating an urgent need to speak with him because it was taking too long to authorize an MRI and she was afraid petitioner was going to lose his vision. (*Id.* at 255.) Dr. Kashino returned the call the same day and spoke to petitioner. He advised that petitioner needed to return to the neurologist for any MRI order. (*Id.* at 255.) Petitioner reported headaches of 6 out of 10 on the pain scale, but advised that his joint pain and rashes had resolved.[8] (*Id.*)

Petitioner returned to Dr. Bhattacharya on October 31, 2012. (Ex. 7, pp. 3-6.) Dr. Bhattacharya noted that petitioner had originally been seen for aseptic meningitis, but that he has continued to experience headaches on and off. (*Id.* at 4.) He assessed right trigeminal autonomic cephalgia and ordered a brain MRI to evaluate. (Ex. 7, p. 6.) This MRI was conducted on November 6, 2012, and was largely unremarkable. (*Id.* at 1-2.)

Petitioner was seen by Dr. Kaufmann for a further follow-up exam on November 2, 2012. (Ex. 2, p. 251.) During this visit, petitioner reported continued pressure in his head, tingling over his right head and face, a transient rash that would appear in the mornings, and tightness of the throat muscles. (*Id.*) Dr. Kaufmann noted that rickettsial infections were unlikely, but not excluded, and that there was a remote possibility of typhus despite petitioner's negative tests. (*Id.*) Dr. Kaufmann noted that "a unifying diagnosis remains elusive" and that the symptoms petitioner reported were "most suggestive of allergic or immunologic issue." (*Id.* at 252.) Dr. Kaufmann believed that an allergy/immunology opinion would be helpful to assist diagnosis "in the challenging case of this patient." (*Id.*)

On November 8, 2012, petitioner reported to UCLA Medical Center Emergency Services with a chief complaint of dizziness and tingling in his fingers, as well as "rashes on [bilateral upper extremities] only in the morning." (Ex. 9, p. 1.) Petitioner was seen by the Internal Medicine department at UCLA Health on November 21, 2012. (*Id.* at 4.) He reported headache, pain in his neck, jaw, hands, feet, knees, wrists, and elbows, and a morning rash on his biceps and forearms. (*Id.* at 5.) Petitioner was

[8] During the hearing I asked petitioner whether there were any symptoms beyond the headache of 6 out of 10 that he reported by phone to Dr. Kashino that raised a concern for loss of vision. He could not recall any other symptoms. (Tr. 52.)

referred to immunology with a diagnosis of an unclear syndrome and chronic fatigue. (*Id.*)

Petitioner was referred to Stanford Hospital and Clinics for further evaluation with an infectious disease specialist at about this time. (Ex. 2, p. 250.) He had a follow up appointment with Dr. Kaufmann on December 10, 2012; however, Dr. Kaufmann remained unable to identify any unifying diagnosis and indicated he would await the conclusion of petitioner's evaluation at Stanford. (*Id*. at 249.) Petitioner also saw Dr. Kashino on December 10, 2012, and Dr. Kashino similarly deferred further testing pending petitioner's infectious disease evaluation from Stanford and an upcoming rheumatology appointment. (*Id*. at 247.) Dr. Kashino questioned whether there is a psychological aspect to petitioner's condition, but noted that petitioner felt his rashes prove he has an infectious or immunologic condition. (*Id.*)

Petitioner was examined by Dr. Julie Parsonnet on December 7, 2012, for an infectious disease consultation where he underwent several tests and a physical examination. (Ex. 2, p. 229-245.) He provided Dr. Parsonnet with a list of symptoms including daily head pressure and headaches, daily joint pain, a speckled rash under his forearms one to three mornings per week, constant fatigue, right trigeminal nerve tingling, a tightness of his neck muscles, intense dizziness and imbalance from November 13 to November 15, heart palpitations one to three days per week, constant soreness on the back of his neck, daily muscle fasciculations, and sore lymph nodes.[9] (*Id.* at 234.) Dr. Parsonnet felt that, especially given his extensive workup and lack of any diagnostically useful test results, fibromyalgia would be the leading possibility among several conditions given the chronicity and lack of inflammatory markers. (*Id*. at 236-37.) Dr. Parsonnet also felt a component of TMJ[10] or migraine remained possible, though those conditions would not explain the myalgia and arthralgia. (*Id*.) Dr. Parsonett intended to follow up to discuss therapeutic options after petitioner had seen rheumatology. (*Id*.)

Petitioner also saw rheumatologist Dr. Lester Miller on December 11, 2012, for an evaluation of his joint and muscle pain. (Ex. 13, p. 7; Ex. 2, pp. 221-28.)[11] Dr. Miller noted no abnormalities upon review of petitioner's physical exam and lab work, with no

[9] Dr. Kashino also confirmed that he was provided a copy of this list for scanning into his chart. (Ex. 2, p. 246.) Petitioner explained during the hearing that he prepared the list over time as his symptoms were developing. (Tr. 52-53.) Initially he could not recall whether he continued to update the list after presenting it to Dr. Parsonnet; however, an updated version of the chronology with entries as late as June of 2015 was later filed as Exhibit 54.

[10] Petitioner first raised his trigeminal neuralgia and possible TMJ with his dentist on November 21, 2012. (Ex. 26, p. 1.) Petitioner's dentists do not appear to have provided any care or diagnosis relevant to this case. (Tr. 29-30; Exs. 26-27.)

[11] Two pages of handwritten notes regarding Dr. Miller's December 11 encounter are included in Exhibit 13, which is a filing of Dr. Miller's records; however, Dr. Miller also prepared an extensive letter report to Drs. Kashino and Kaufmann that is contained in the Dominican Medical Group records at Exhibit 2 and is also reproduced at Ex. 13, pp. 7-10.

evidence of inflammatory polyarthritis on examination and normal inflammatory markers in bloodwork from August 30 through December 5, 2012. (Ex. 13, pp. 8-9.) Dr. Miller's clinical impression was that petitioner had arthralgia, head pressure, periodic rash, fatigue, sensation of muscle tightening, and other non-specific symptoms, but with no clear signs of reactive arthropathy, connective tissue disease, or autoimmune process. (Ex. 13, p. 9.) Dr. Miller noted that "the spectrum of [petitioner's] symptoms do not fit a particular infectious process and in my opinion do not fit a particular rheumatic disease . . . ." (*Id*.) He doubted that petitioner had fibromyalgia. (*Id*.) Dr. Miller left open the possibility of a vaccine-reaction, noting that it is "conceivable" given that Hepatitis A vaccine has been documented as causing non-specific symptoms such as headache, malaise, diarrhea, dizziness, nausea, anorexia, fever, skin rash, and vomiting. (*Id.* at 9-10.) However, he indicated "[t]here is no way at this point to prove or disprove that speculation." [12] (*Id*. at 10.) He recommended continued observation and NSAIDs for pain relief, but recommended against any further antibiotics. (*Id*.)

Petitioner returned to Dr. Parsonnet on December 21, 2012. (Ex. 12, pp. 20-21.) Dr. Parsonnet recorded an interval history and noted that there is no consensus among petitioner's treaters regarding his symptoms. (*Id.* at 20.) Petitioner stressed that his symptoms improved while he was on azithromycin and Dr. Parsonnet expressed willingness to prescribe another course, but otherwise did not recommend any further testing. She felt consultation with a dentist remained appropriate along with further follow up with a neurologist. (*Id*. at 21.)

Petitioner was later seen for an allergy and immunology consultation with Drs. Tiffany Kim (resident) and Melinda Braskett (attending) at UCLA Medical Center on January 11, 2013. (Ex. 9, pp. 6-9.) Dr. Kim's physical exam indicated tension in the neck and shoulder muscles, but there was no indication of fasciculations and joints were unremarkable. (*Id*. at 7.) No rashes or lesions were noted. (*Id.*) Lab results were unremarkable. (*Id*.) In addition to his post-vaccination medical history, petitioner also related that he had three prior allergic reactions to antibiotics as a child (hives after penicillin, photosensitivity and neuropathy after cipro, and rash and hives after erythromycin). (*Id*. at 6.) Dr. Kim felt that a reaction to vaccination was "possible" and felt that the prior allergic reactions to antibiotics could suggest "an immunologic predisposition." (*Id*. at 7.) Dr. Kim indicated that the history of migratory arthritis and rash, especially between the fingers, could suggest a now resolved serum sickness. (*Id.*) Petitioner's main complaints at this visit were throat tightening, muscle fasciculations, and fatigue. No "clear etiology" was identified, but the assessment included "[q]uery post vaccine immunologic reaction versus unknown post viral syndrome" while indicating that persistent muscle fasciculations represented a separate

[12] Significant to assessing the contours of Dr. Miller's openness to "speculation" regarding vaccine causation of non-specific symptoms, Dr. Miller's report incorrectly states that petitioner has had arthralgia and myalgias beginning August 8, 2012. (Ex. 13, p. 7.) This is not consistent either with petitioner's contemporaneous medical records or with the written timeline of symptoms petitioner first provided to Dr. Parsonnet and which Dr. Miller indicated he had reviewed and would not repeat. (Ex. 2, pp. 230-31; Ex. 13, p. 7). Arthralgia and myalgia were not reported at petitioner's earliest post-vaccination encounters and Dr. Kashino specifically confirmed the absence of both during his August 28, 2012 encounter. (Ex. 2, p. 268.)

assessment in need of evaluation by a peripheral nerve specialist. (*Id*.) Further subspeciality coordination, including with a rheumatologist, was recommended. (*Id*.) Upon review, Dr. Braskett noted petitioner's turbinates were inflamed with visible postnasal drip and that his lab results were negative for immune complexes and with normal erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). (*Id*. at 8.) Her impression included "[a]dverse reaction to vaccine" and "[l]ikely serum sickness resolved" and "[p]ersistent fasciculations, unclear etiology – possibly post immunization or post viral." (*Id*.)

Petitioner was then seen by UCLA neuromuscular specialists Drs. Perry Shieh and Elba Maldonado on January 18, 2013, for evaluation of his muscle fasciculations and tightness of his throat muscles. (Ex. 9, p. 9.) Petitioner expressed concern that his progressing fasciculations might be due to a demyelinating condition. (*Id*.) The fasciculations were observed at the pectoral and abdominal muscles, but petitioner's physical and neurological testing was all normal, and Drs. Shieh and Maldonado ultimately diagnosed him with likely "benign fasciculation syndrome that the etiology of which is unknown." (*Id.* at 11.) The doctors also expressed the possibility that the syndrome "could" be "due to post-vaccine immunologic reaction or postviral syndrome." (*Id.*) Thereafter, Dr. Braskett added an addendum to her record to notate that petitioner's fasciculations are benign. (*Id.* at 8.)

Petitioner was seen by immunologist Donna Felsenstein, M.D., at Massachusetts General Hospital on February 4, 2013. (Ex. 14, p. 17.) Petitioner provided an extensive history; however, Dr. Felsenstein summarized "fatigue which is somewhat improved as well as fasciculations" as being primary complaints at this encounter. (*Id*. at 19.) Review of systems also noted complaints of tingling in his hands, feet, and chest, tenderness at certain points on his chest. (*Id.* at 18.) In addition to extensive lab work, all of which was negative, Dr. Felsenstein reviewed a photograph of a prior rash on petitioner's arm which she described as erythematous maculopapular. (*Id.* at 18-19.) Physical exam was normal and Dr. Felsenstein stressed the lack of any weakness on exam. (*Id.* at 18-19.) Nonetheless, she felt the fasciculations were concerning and recommended a third neurology opinion. (*Id*. at 19.) Dr. Felsenstein concluded that the etiology of petitioner's condition remained unclear, but felt it interesting that petitioner's girlfriend had experienced a mono-like illness around the time his condition began. (*Id*.)

Petitioner returned to Dr. Kashino on February 7, 2013. (Ex. 2, pp. 215-17.) Petitioner reported worsening muscle fasciculations involving his whole body, vibratory sensations in his hands and feet, tightness around his temples and throat, slightly improved fatigue, and improved joint pain after removing gluten from his diet. (*Id.* at 215.) Dr. Kashino noted that "[t]hree physicians have felt that his symptoms were due to vaccines."[13] (*Id*.) Dr. Kashino reviewed petitioner's symptoms but offered no further

[13] Dr. Kashino identified the three doctors as Dr. Kaufmann, Dr. Miller, and Dr. Parsonnet. (Ex. 2, p. 215.) Based on my review of each physician's encounter records, Dr. Kashino significantly overstates the degree to which any of the three supported vaccine causation. Dr. Kaufmann indicated that petitioner's symptoms could be immunologic, but stressed that a unifying diagnosis remained "elusive" and only included a vaccine reaction "per patient perception" among his assessments. (*Id*. at 262.) Dr. Miller felt that petitioner's spectrum of symptoms did not fit any identifiable condition. He noted that vaccine-

diagnostic assessment and awaited any further developments based outstanding lab work from the Massachusetts General Hospital evaluation. (*Id.* at 217.)

On March 4, 2013, petitioner was seen by Dr. Grant de la Motte at the Palo Alto Medical Foundation, Santa Cruz Division, for a neurology consult. (Ex. 2, pp. 167-71.) Petitioner recounted his symptoms and explained that he now believed he was experiencing an "Epstein Barr virus recurrence . . . lyme . . . [or] a vaccine reaction." (*Id.* at 168.) Dr. de la Motte reviewed petitioner's prior records and noted that "[l]aboratory work up was extensive and included an impressive list of infectious diseases and metabolic diseases. The testing was all normal." (*Id.* at 171.) Dr. de la Motte's physical exam was also normal. (*Id.* at 170-71.) Dr. de la Motte assessed subjective muscle twitching, paresthesia, and fatigue. He concluded:

> This young man is presenting with multiple somatic symptoms that do not fit into a neurologic pattern of disease, and therefore, not localizable. His neurologic exam is normal. I do not see any fasciculations. I doubt his symptoms will be associated with any defined pathology. I expressed my concern that an EMG study is low-yield, but he is interested in confirming the presence of fasciculations. He understands that fasciculations are nonspecific and can be seen in the normal population, but he would still like to proceed with the study.

(*Id.* at 167.)

On April 1, 2013, petitioner received an echocardiogram from Drs. Raj Singh and Jay Johnson. (*Id.* at 204.) Petitioner's echocardiogram was unremarkable outside of trace mitral regurgitation and trace tricuspid regurgitation. (*Id.* at 205.) On April 10, 2013, Dr. Kashino saw petitioner and ordered a cognitive metabolic panel, thyroid studies, and Lyme titers. (*Id.* at 202.)

During this same period, petitioner was seen by neurologist Dr. Neelam Goyal for EMG and nerve conduction tests at Stanford Hospital on April 19, 2013. (Ex. 2, p. 163.) Dr. Goyal concluded that "[t]hese electrodiagnostic studies are normal without evidence

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causation was "conceivable," but considered it unprovable "speculation." (Ex. 13, pp. 9-10.) Dr. Parsonett did include Reiters syndrome, a post-infectious syndrome, in her differential diagnosis, but at the time of her consultation with petitioner felt that his condition was most likely to be fibromyalgia. (Ex. 2, p. 245.) Dr. Kashino's summary of petitioner's prior consultations appears in the "HPI" section of his record. It is not clear whether it is based on any review of records or petitioner's own description of his prior encounters. Dr. Kashino did reference that Dr. Parsonnet had called the CDC with regard to this case. (Ex. 2, p. 215.) As of April 28, 2013, Dr. Parsonnet recorded: "Discussed with national vaccine safety group (Clinical Immunization Safety Assessment Network at CDC) who felt symptoms are unlikely to be related to immunizations. They were concerned about toxic exposure or primary neurologic process." (Ex. 12, p. 35.) On July 12, 2013, Dr. Parsonnet discussed with petitioner the fact that she had contacted the CDC and that the CDC had not ever seen reaction of this duration. (Ex. 12, p. 66; *see also* Ex. 14, p. 12 (copy of e-mail by Dr. Parsonnet explaining committee conclusions in greater detail).) Nothing in the record of petitioner's July 12, 2013 encounter suggests Dr. Parsonnet had become more persuaded of a vaccine reaction after conferring with the CDC. She sought to persuade petitioner not to pursue a spinal MRI, a lumbar puncture, or a course of steroid treatment. (*Id.*)

of a neuropathy, neuromuscular junction pathology, or motor neuron disease." (*Id.* at 165.) In a later letter to Dr. Parsonnet dated July 12, 2013, Dr. Goyal wrote that she did not see any evidence of clear pathology affecting petitioner's large sensory fibers or motor system. (Ex. 2, pp. 155-58.) She further noted that there is no evidence of pathology for petitioner's fasciculations after reviewing the EMG nerve conduction study and noted the symptom can be heightened by stress or anxiety. (*Id.* at 158.) While Dr. Goyal noted "scant fibrillation potentials" on petitioner's EMG, she explained that their significance was unclear but possibly related to mild spondylitic disease of the spine and unlikely to be related to petitioner's paresthesias or fasciculations. (*Id.* at 163-65.) Dr. Goyal was unable to make a diagnosis and expressed interest in a dedicated lumbar spine MRI for further evaluation. (*Id.* at 158.) Dr. Goyal also recommended autonomic testing given that petitioner's initial presentation included lightheadedness. (*Id.*)

By June 13, 2013, Dr. Kashino noted that petitioner was "slowly improving" but was still unable to make a unifying diagnosis. (*Id.* at 199.) Dr. Kashino indicated that Dr. Felsenstein from Massachusetts General Hospital had prescribed doxycycline and requested a repeat of petitioner's borrelia test, suggesting further suspicion of Lyme disease. (*Id*. at 198.) Yet, on July 17, 2013, Dr. Kashino indicated that "[t]he consensus is that this is probably a post-vaccine reaction." (*Id*. at 196.) The specific basis for this statement is not indicated; however, in including a probable adverse effect of vaccines in his assessment, Dr. Kashino reiterated the notation from his February 7, 2013, record that the conclusion was supported by three physicians.[14] (*Id*. at 197.) Additionally, Dr. Kashino observed that petitioner had just completed his course of doxycycline as prescribed by Massachusetts General Hospital and that Stanford had ordered MRI of petitioner's spine. (*Id*. at 196.) Subsequently, on July 30, 2013, petitioner called Dr. Kashino's office to request that he order the Lyme disease tests recommended by Massachusetts General Hospital. (*Id*. at 195.) Petitioner also later underwent lumbar MRI on August 12, 2013. (Ex. 2, p. 148.) Dr. Goyal reviewed petitioner's MRI and noted "mild degenerative changes of the lower lumbar spine" and "no significant central or neuro-foraminal narrowing at any level." (*Id.*) Dr. Kashino's July 17 suggestion of any consensus is perplexing given his awareness of this ongoing investigation from two different practice groups. As of September 23, 2013, Dr. Felsenstein noted the cause of petitioner's condition remains undefined despite petitioner reporting that other doctors had concluded it was vaccine related. (Ex. 14, p. 5.)

On September 4, 2013, petitioner expressed to Dr. Kashino that he was feeling "quite a bit better." (Ex. 2, p. 192-93.) Dr. Kashino characterized petitioner's condition as "probable adverse effect of vaccines" and again noted that "Three physicians support this, Lester Miller, MD; a southern California allergist/immunologist; and Dr. Julie

[14] In that regard, refer back to n. 13, *infra*. In fact, one of these three physicians, Dr. Parsonett, specifically recorded in her own records as of December 21, 2012, that there was no consensus among petitioner's treating physicians regarding his symptoms. (Ex. 12, p. 20.) By that time, petitioner had already consulted with Drs. Miller and Kaufmann, the other two physicians contributing to the purported consensus.

[Parsonnet], MD, infectious disease at Stanford." [15] (Ex. 2, p. 193.) Dr. Kashino concluded this visit by clearing petitioner to return to work on October 1. 2013. (*Id.* at 191.) Petitioner had no significant medical treatment for the next six months. However, he continued to request further tests and treatments. (Ex. 2, p. 190 (10/4/13 request for thyroid test), p. 189 (10/14/13 request for stress test and additional lab work), p. 188 (10/22/13 request for physical therapy referral for myalgia), p. 186 (12/6/13 request for redo of prior bloodwork plus prescription for Neurontin).

On March 7, 2014, petitioner presented to neurologist Safwan Jaradeh for the autonomic testing recommended by Dr. Goyal the prior July. (Ex. 12, p. 110.) Dr. Jaradeh's testing revealed "mild to moderate autonomic neuropathy involving the sympathetic vasomotor and cardiovascular fibers" as well as "parasympathetic cardiovascular and baroreflex sparing." (*Id.* at 111.) Dr. Jaradeh also noted that the tilt table findings indicated significant orthostatic hypotension and tachycardia. (*Id.*) Petitioner left this visit with a post-procedure diagnosis of orthostatic hypotension and postural orthostatic tachycardia syndrome (POTS).[16] (*Id.* at 110.)

Petitioner was not seen again until the following September when he presented to Dr. Kashino on September 11, 2014. In the interim he was reportedly traveling in Europe for about four months. (Ex. 23, p. 55.) Dr. Kashino appears to have suggested that petitioner benefited from a period of ignoring his health symptoms.[17] (*Id*.) At this visit, petitioner reported new onset of perioral numbness. (*Id.*) Petitioner expressed a desire to post a list of his symptoms online so his physicians could more easily comment. (*Id*. at 57.)

On September 17, 2014, petitioner presented to dermatologist Molly Shields, M.D. (Ex. 25, p. 1.) He reported speckled rashes appearing in the morning (for about one hour) for the past two years. (*Id.*) He wondered if they were vaccine caused. (*Id*.) Dr. Shields indicated that she did not know the cause of petitioner's cutaneous eruption,

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[15] In that regard, refer back to n. 13-14, *infra*. This statement is also repeated in future records, but will not be further addressed.

[16] These diagnoses are questionable based on the findings recorded by Dr. Jaradeh. POTS is defined as a heart rate increase of 30 beats per minute within 10 minutes of standing of head up tilt in the absence of orthostatic hypotension. Usually, this results in a standing heartrate of 120 beats per minute or higher. (Eduardo Benarroch, *Postural Tachycardia Syndrome: A Heterogeneous and Multifactorial Disorder,* 87(12) Mayo Clin. Proc. 1214 (2012) (Ex. A, Tab 1).) In this case, Dr. Jaradeh indicted that petitioner's tilt table test indicated tachycardia plus significant orthostatic hypotension. And, in any event, petitioner did not exceed a 30 beats per minute increase until 15 minutes into the test and his heartrate reached a maximum of 117 beats per minute after 22 minutes. (Ex. 12, pp. 111-12.) Nor, for that matter, did petitioner meet the consensus criteria for orthostatic hypotension. The consensus criteria requires at least a 20 mm drop is systolic blood pressure occurring within three minutes of standing. (Phillip Low and Wolfgang Singer, *Management of neurogenic orthostatic hypotension: an update,* 7 LANCET NEUROL. 451 (2008) (Ex. A, Tab 5).) Petitioner ultimately experienced a 36 mm drop in systolic blood pressure, but blood pressure drop during the first 16 minutes after tilt was described as "minimal." (Ex. 12, p. 112.)

[17] The specific notation is somewhat hindered by a typographical error. The record states: "He did well by ignored his health symptoms." (Ex. 23, p. 55.) It seems reasonable to interpret this as indicating "[h]e did well by ignore[ing] his health symptoms."

but suggested it may be vascular and expressed concern regarding a rheumatologic disorder, though petitioner's presentation did not fit Still's disease or juvenile rheumatoid arthritis. (*Id*. at 7.) Dr. Shields did not visualize the rashes, but recommended a skin biopsy when a rash is present. (*Id*.; *see also* Ex. 19, p. 18.)

Petitioner also returned to Dr. Goyal the same day. (*Id*.) He reported "good energy" and "minimal joint pain," but indicated he had occasional jaw pain, mild temple and occipital pain (primarily right), and rashes appearing in the morning. Dr. Goyal noted fasciculations, chest discomfort, and "odd sensations," to still be present, and perhaps worsened. (*Id*.) A Holter monitor reportedly showed premature ventricular contractions and petitioner reported sudden onset of perioral tingling and tingling of the right hand which occurred while he was in Europe. (*Id*.) Physical exam was noted to be normal except for subjective pinprick loss over the hand. Dr. Goyal felt the paresthesias was benign, likely related to headache or anxiety, but agreed to a repeat brain MRI. (*Id*. at 19.) Noting the abnormalities previously found on autonomic testing, Dr. Goyal also noted the possibility of small fiber polyneuropathy and agreed to refer petitioner to an autonomic clinic for further evaluation. (*Id*. at 19-20.)

Petitioner was seen again by dermatologist Dr. Shields for a punch biopsy on October 13, 2014. (Ex. 23, pp. 2-6.) Dr. Shields observed "[p]atches and macular erythema faint in quality in 2-3 mm macular coalescent to plaques linear quality" and a sample was taken from the left pretibial region. (*Id*. at 2.) Petitioner's punch biopsy was interpreted by Dr. Laura Pincus. Her dermatopathology report indicated "relatively sparse perivascular infiltrate with early neutrophilic forms." (*Id.* at 5.) The report further noted that "this could represent Still's disease, [but] this pattern of infiltration can be seen in neutrophilic urticarial dermatosis as well." (Ex. 23, p. 5.) However, the report also explained that neutrophilic urticarial dermatosis patients "often have an associated systemic condition, such as Schnitzler's syndrome, lupus erythematosus, or a hereditary autoinflammatory fever syndrome. Therefore, the systemic symptoms you mention might be explained by one of these conditions rather than Still's disease." (*Id.*) She noted, however, that "[c]onvential urticarial or neutrophilic urticaria are possible diagnostic considerations for this eruption as well." (*Id*.)

Petitioner had a cardiology consultation with Jay A. Johnson, M.D., on October 9, 2014. (Ex. 23, pp. 53-54.) He underwent a stress test and echocardiogram. (*Id.* at 53.) The stress test revealed that petitioner had an "outstanding exercise capacity" and the echocardiogram showed "trivial" mitral and tricuspid valve regurgitation. (*Id.* at 54.) Dr. Johnson concluded that petitioner had no evidence of structural or ischemic heart disease and no evidence of significant arrhythmias or electrical abnormalities. Dr. Johnson noted the prior finding of premature atrial contraction which may result in symptoms, but indicated they do not appear pathologic. (*Id*.) Dr. Johnson felt petitioner was "extremely sensitive to his body and is fixated on these many multiple mild somatic complaints . . . I cannot suggest any unifying diagnosis and would be interested in input from a psychiatric specialist." (*Id.*) He indicated that he cannot offer a unifying diagnosis and recommended input from a psychiatric specialist. (*Id*.)

On October 16, 2014, petitioner had a follow up consultation with Dr. Jaradeh at the Stanford neuroautonomic clinic. (Ex. 19, pp. 45-46.) Dr Jaradeh suspected that petitioner "had a form of serum sickness following his immunization. This may have left him with a transient polyradiculitis and subsequent autonomic dysfunction." (*Id*. at 46.) Dr. Jaradeh also noted, however, that "it is somewhat unusual to continue to have arthralgias as well as rash." (*Id.*) Dr. Jaradeh ordered additional bloodwork, including adrenal function, and suggested a skin biopsy might be appropriate. (*Id*.)

Petitioner was seen by dermatologists Tina Bhutani and Timothy Berger on November 24, 2014 based on a referral from Dr. Shields for a consultation regarding neutrophilic urticarial dermatosis. (Ex. 23, pp. 1, 4.) The doctors noted that "although the biopsy may be consistent with Still's disease or neutrophilic urticaria, we do not feel that the patient's clinical presentation is classic for either of these syndromes," because petitioner's ferritin and ESR were normal "which goes against the diagnosis of Still's disease." (*Id.*) "In addition," the doctors continued, "neurologic manifestations are uncommon for both Still's disease as well as neutrophilic urticaria with systemic symptoms." (*Id.*) The doctors noted that of the variety of conditions that could be consistent with petitioner's rashes, each one "may result in very significant stimulation of the immune system and a persistent cytokine/neutrophil response (Sweet's syndrome represents such a syndrome)." (*Id.*) The doctors noted that petitioner had no symptoms of inflammatory bowel disease, and that while Bechet's is possible, he lacked oral or genital ulcerations and ocular findings—which would be an atypical presentation. (Ex. 23, p. 2.) Thus, the doctors concluded, the most likely diagnosis given petitioner's symptoms is a "recurrent inflammatory condition that may have been triggered by a significant antigen exposure," such as Sweet's. (*Id.*) The attending note clarifies that until such time as petitioner's presentation would develop to be more characteristic of a defined condition, "we often diagnose these patients as 'Neutrophilic Dermatosis, NOS' keeping our minds open as to possible etiopathogenesis." (*Id*.)

Following his visit to Drs. Bhutani and Berger, petitioner ceased seeing specialists and relied primarily on Dr. Kashino for treatment. (Exs. 31, 50.) During subsequent visits to Dr. Kashino's office, petitioner continued to report symptoms of worsening generalized muscle fasciculations involving his whole body, vibratory sensations in his hands and feet, tightness around his temples and throat, and improving fatigue and joint pain which he believed were related to his August 3, 2012 vaccinations. (*E.g.,* Ex. 31, p. 19.) On August 8, 2017, petitioner returned to Dr. Kashino. (Ex. 50, pp. 6-9.) Dr. Kashino noted that he had not seen petitioner since September 9, 2015, but that petitioner had returned to document that he had not improved relative to his alleged vaccine reaction. (*Id*. at 6.)

b. As Reflected in Petitioner's Affidavit and Testimony

On May 14, 2015, petitioner filed two affidavits in support of his claim. (Exs. 21, 22.) Petitioner explained that prior to his vaccination he was healthy and active, exercising regularly, and often traveling, hiking, and camping. (Ex. 21, p. 1.) He affirmed that shortly after he was vaccinated, he began to feel unusually tired with bouts

of dizziness, neck soreness, increasing fatigue, and "a strange head pressure running from temple to temple" around the back of his head. (*Id.* at p. 2.) He detailed his initial visit to urgent care where he was diagnosed with a sinus infection and prescribed Flonase and a Z-Pack. Petitioner indicated that the medications did not help and that his symptoms became progressively worse. (*Id.*) Petitioner stated that he attempted to maintain an active lifestyle despite his symptoms, but that he began to experience joint pain which required frequent breaks. (*Id.* at 3.) Petitioner further explained that his symptoms significantly impaired his job performance, required him to rest during his workday, and ultimately led him to take medical leave for eight months before finally quitting. (*Id.*) At the time of writing his affidavit, petitioner had moved back with his parents and was still not working. (*Id.*) Petitioner still experienced "rashes, joint pain, some fatigue, fasciculations which seem to be increasing in frequency and severity, a buzzing/vibration sensation across [his] chest, and head pressure around [his] right temple, among other symptoms," at the time of writing his affidavit. (Ex. 21, p. 4.) The second affidavit that petitioner filed affirmed that he has not initiated any civil actions or collected any awards or settlements in connection to his alleged injury. (Ex. 22, p. 1.).

During the hearing, petitioner testified that he first noticed fatigue, head pressure, neck pain, and lightheadedness about 4-5 days following his vaccination. (Tr. 12-14.) He did not recall having any sinus congestion at the time and indicated that neither Flonase nor Claritin alleviated his symptoms. (Tr. 15-16.) He did not address the azithromycin discussed above. He indicated pain at the vaccination site lasted for a few weeks, but the joint pain became severe around Thanksgiving. (Tr. 27-29.) Petitioner discussed his medical history in some detail and confirmed that Drs. Kaufmann, Bahttacharya, Braskett, and Kim never offered any definitive diagnosis. (Tr. 19-20, 21.) He suggested that Dr. Jaradeh attributed his condition to vaccination based on a perceived temporal relationship. (Tr. 23.) Petitioner has never sought any follow up treatment for POTS or for dysautonomia. (Tr. 47.) Petitioner explained that Drs. Bhutani and Berger were the first to suspect Sweet's syndrome in November of 2014 (Tr. 23-24); however, he also confirmed that he was never subsequently treated on the basis of having Sweet's syndrome (Tr. 47).

Petitioner also explained that, by the time of the hearing, he had returned to work with a more flexible schedule. (Tr. 47-50.) His medical leave ultimately lasted between six months to a year. (*Id.*) Petitioner stressed that "[i]t was really distressing to see so many specialists and people who I thought would have been able to get to the bottom of what was going on who really didn't – really didn't have any way to treat it." (Tr. 31-32.) He described it as the most stressful experience of his life. (Tr. 32.)

c. As Reflected by Dr. Jaradeh's Letter

On March 23, 2016, Dr. Jaradeh drafted a letter to petitioner's former counsel supporting this claim. (Ex. 30.) Dr. Jaradeh reiterated petitioner's prior clinical course and observed that autonomic testing confirmed "some autonomic nerve impairment involving particularly the sympathetic fibers," but noted that clinical examination was otherwise normal except for the fasciculations. (Ex. 30, pp. 1-2.)

Dr. Jaradeh indicated that his initial clinical impression was autonomic neuropathy. (*Id*. at 2.) Based on the reported history, he further felt that the problem was likely related to his vaccination and perhaps with further contribution from his subsequent treatment. (*Id*.) He did not specify which treatment(s). Dr. Jaradeh theorized as follows:

> Occasionally, this combination [of vaccines] causes some type of an immune reaction known as serum sickness where there are circulating antibodies to the vaccine that somehow provide some type of inflammation involving the skin, the joints, as well as the nervous system, in this case autonomic as well as neuromuscular fibers. A less likely alternative would be that he had a reaction to the infection that he had with the sinus, or the antibiotic, but this is less plausible given the fact that he has received this antibiotic in the past and never had a reaction to it.

(*Id*.) He concludes that "[i]t is my medical opinion that his neurologic situation has closely followed, and is related to the vaccination." (*Id*.)

IV. Expert Reports

a. Petitioner's Expert

i. Carlo Tornatore, M.D.

Petitioner filed an expert report by neurologist Dr. Carlo Tornatore on January 24, 2018 to support his claim. (Ex. 32.) Dr. Tornatore also testified during the hearing and was accepted without objection as an expert in neurology.[18] (Tr. 80.) Dr. Tornatore opined that petitioner suffered from post-vaccinal Sweet's syndrome and serum sickness. (Ex. 32, p. 5.)

Dr. Tornatore described Sweet's syndrome as a condition of the skin that is distinct from classical auto-immunity because it involves "aberrant control of the innate immune response, often through interleukin (IL)-1-mediated pathways," as opposed to "T-cell-mediated or major histocompatibility complex-related processes." (*Id.*) He

[18] Dr. Tornatore is a Professor and Chairman of the Department of Neurology at Georgetown University Medical Center and has been board certified in Neurology since 1991. (Ex. 32, p. 1.) He is also the Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital. (*Id*.) He is Executive Director of the Georgetown Multiple Sclerosis Patient Centered Specialty Home as well. (*Id*.) He completed his residency in Neurology at Georgetown and a post-doctoral fellowship at the National Institutes of Neurologic Disorders and Stroke at the National Institutes of Health where he studied the interaction of viruses and immune system. (*Id*.) Following his fellowship, Dr. Tornatore joined the faculty at Georgetown where he has been the Director of the Multiple Sclerosis Center for 21 years. (*Id*.) Under Dr. Tornatore's direction, the MS Center currently follows 210 patients with acute disseminated encephalomyelitis (ADEM), 95 patients with neuromyelitis optica (NMO), 340 patients with transverse myelitis (TM), 45 patients with central nervous system vasculitis, 98 patents with neurosarcoidosis, and 45 patients with various other inflammatory conditions of the brain and spinal cord including Bechet's and Susac's diseases. (*Id.)*

explained that in auto-inflammatory diseases such as Sweet's, "autoantibody titers are absent or low and as opposed to lymphocytes, neutrophils and macrophages are most often the effector cells." (Ex. 32, p. 5) (citing Aditi S Murthy & Kieron Leslie, *Autoinflammatory Skin Disease: A Review of Concepts and Applications to General Dermatology*, 232 DERMATOLOGY 534 (2016) (EX. 33).) Dr. Tornatore further explained that autoinflammatory and autoimmune conditions are not mutually exclusive because mediators of auto-inflammatory diseases "likely play a role in a variety of conditions thought of as 'autoimmune'." (*Id.*) Further, according to Dr. Tornatore, because neutrophilic-mediated processes play a significant role in auto-inflammatory conditions such as Sweet's, "it follows that auto-inflammation may play an important role in dermatoses where neutrophils are predominant." (*Id.*)

Dr. Tornatore further illustrated the distinction between auto-inflammatory and auto-immune responses by noting that it is "innate immunity" which "directly causes tissue inflammation" in auto-inflammatory diseases while the role that innate immunity plays in auto-immune diseases is less clear. (*Id.*) However, Dr. Tornatore noted, it is possible that innate mechanisms activate the adaptive immune responses that are the primary mediators of auto-immune diseases. (*Id.*) Ultimately, Dr. Tornatore suggested that "[a]uto-inflammation to autoimmunity likely represents a spectrum of disease processes . . . with many common skin conditions with overlapping features. Prime examples of dermatoses closer to the auto-inflammatory end . . . are pyoderma gangrenosum and Sweet's syndrome both . . . characterized by sterile neutrophilic infiltrates." (*Id.*) (internal citations omitted).

Dr. Tornatore explained that "Classic Sweet's syndrome [typically] occurs in middle-aged women after a nonspecific infection of the respiratory or gastrointestinal tract. Raised erythematous plaques with pseudo-blistering and occasionally pustules occur on the face, neck, chest, and extremities, accompanied by fever and general malaise." (Ex. 32, p. 5) (citing Peter von den Driesch, *Sweet's Syndrome (acute febrile neutrophilic dermatosis)*, 31 J. AM. ACAD. DERMATOLOGY 535 (1994) (Ex. 34).) Further, Dr. Tornatore explained that "involvement of the eyes, joints, and oral mucosa as well as internal manifestations . . . in the lung, liver, kidneys, and central nervous system has been described." (*Id.*) Dr. Tornatore explained that his review of the literature found that onset of Sweet's has been associated with a variety of different vaccinations including BCG, pneumococcal, and influenza.[19] (*Id.* at p. 6)

[19] Citing Boris Radeff & Monika Harms, *Acute Febrile Neutrophilic Dermatosis (Sweet's Syndrome) Following BCG Vaccination*, 66 ACTA DERMATO-VENEREOLOGICA 357 (1986) (Ex. 35); Paul R. Maddox & Richard J. Motley, *Sweet's Syndrome: a severe complication of pneumococcal vaccination following emergency splenectomy*, 77 BRIT. J. OF SURGERY 809 (1990) (Ex. 36); Olivier Capentier et al., *Sweet's Syndrome after BCG Vaccination*, 82 ACTA DERMATO-VENEROLOGICA 221 (2002) (EX. 37); Marina Jovanovic et al., *Acute febrile neutrophilic dermatosis (Sweet's syndrome) after influenza vaccination,* 52 J. AM. ACAD. DERMATOLOGY 367 (2005) (Ex. 38); Ronni Wolf et al., *Neutrophilic dermatosis of the hands after influenza vaccination*, 48 INT. J. DERMATOLOGY 66 (2009) (EX. 39); Ana Filipa Pedrosa et al., *Sweet's syndrome triggered by pneumococcal vaccination,* 32 CUTANEOUS AND OCULAR TOXICOLOGY 260 (2013) (EX. 40).

Dr. Tornatore explained that in rare circumstances, a neurological form of Sweet's can occur. This is referred to as "Neuro-Sweet syndrome." (Ex. 32, p. 6) (citing Kinya Hisanaga et al., *Neuro-Sweet disease: Clinical manifestations and criteria for diagnosis*, 64 NEUROLOGY 1756 (2005) (EX. 41); Francesco Drago et al., *Neuro sweet syndrome: a systematic review. A rare complication of Sweet syndrome,* 117 ACTA NEUROLOGICA BELGICA 33 (2017) (EX. 42).) Dr. Tornatore suggested that neuro-Sweet syndrome can affect any part of the nervous system, but most commonly results in meningitis and encephalitis. (Ex. 32, p. 6.) He noted that petitioner "developed cranial and neck pain as well as fatigue shortly after receiving the Hepatitis A and Td vaccinations, symptoms that a treating neurologist felt were consistent with aseptic meningitis." (*Id.*) Dr. Tornatore cited one study that described aseptic meningitis in a neonate with Sweet's syndrome, which he contended "supports the biological plausibility and logical sequence of cause and effect for a vaccination to cause Neuro-Sweet syndrome, with the neurologic manifestation being aseptic meningitis." (*Id.*) (citing Terris R. Dunn et al., *Sweet Syndrome in a Neonate with Aseptic Meningitis,* 9 PEDIATRIC DERMATOLOGY 288 (1992) (Ex. 43).) Further, Dr. Tornatore noted that because petitioner's symptoms began five days after his vaccination, there appears to be a temporal relationship as well. (Ex. 32, p. 6.) He concluded his discussion of Sweet's syndrome by suggesting that symptoms of Sweet's syndrome can persist over several years as petitioner's have. (*Id.*)

Dr. Tornatore also explained, however, that he is of the opinion that petitioner's polyarthralgia was a result of a vaccine-induced serum sickness. One study cited by Dr. Tornatore found that 3% or 14 out of 495 Thai health care professionals who received a flu vaccination developed a serum sickness-like reaction. (*Id.*) (citing Anucha Apisarnthanarak et al., *Serum Sickness-Like Reaction Associated with Inactivated Influenza Vaccination among Thai Health Care Personnel: Risk Factors and Outcomes*, 49 CLINICAL INFECTIOUS DISEASES 18 (2009) (Ex. 44).) He cited another study defining serum sickness as "a type III hypersensitivity reaction that occurs after exposure to foreign antigens . . . Immune complex deposition and activation of the complement cascade can cause fever, polyarthritis or polyarthralgia, and rash and may result from exposure to a heterologous protein . . . or to a drug that lacks protein, such as certain antibiotics." (Ex. 32 p. 6) (citing Claud Ponvert & Pierre Sheinmann, *Vaccine allergy and pseudo-allergy,* 13 EUR. J. OF DERMATOL. 10 (2003) (Ex. 45).) Dr. Tornatore explained that studies have found that medications and antitoxins made with animal serum protein, such as diphtheria and tetanus, have been associated with serum sickness. (Ex. 32, p. 6.) (citing Richard Platt et al., *Serum Sickness-Like Reactions to Amoxicillin, Cefaclor, Cephalexin, and Trimethoprim-Sulfamethoxazole*, 158 J. OF INFECTIOUS DISEASES 474 (1988) (EX. 46); Edgar H. Relyveld et al., *Rational approaches to reduce adverse reactions in man to vaccines containing tetanus and diphtheria toxoids,* 16 VACCINE 1016 (1998) (Ex. 47).) Finally, Dr. Tornatore cited two reports of serum sickness-like reactions to flu vaccinations, but explained that limited data is available regarding incidence, associated risk factors, and outcomes. (Ex. 32, p. 6) (citing James A. Wilde et al., *Effectiveness of Influenza Vaccine in Health Care Professionals: a Randomized Trial*, 281 J. AM. MED. ASSOC. 908 (1999) (Ex. 48); Simin Vessal & Lillian P. Kravis, *Immunologic Mechanisms Responsible for Adverse*

Reactions to Routine Immunizations in Children, 15 CLINICAL PEDIATRICS 688 (1976) (Ex. 49).) Ultimately, Dr. Tornatore concluded that in spite of the limited available data, these studies and case reports nonetheless support a finding of vaccine causation.

During the hearing, Dr. Tornatore testified largely in accordance with his prior report. However, especially when challenged on cross-examination, Dr. Torantore's testimony also stressed an overarching view that vaccine-induced serum sickness and Sweet's syndrome remain a reasonable and likely explanation for petitioner's condition regardless of ambiguities or inconsistencies within the details of petitioner's complex medical history. He characterized himself as taking the "50,000-foot view" of petitioner's presentation and repeatedly urged against "getting into the weed" or "quibbling" over specific findings. (Tr. 124, 151, 153, 162.) Dr. Tornatore stressed that both serum sickness and Sweet's syndrome present with a spectrum of clinical manifestations, suggesting petitioner does not need to perfectly fit the known symptomology of either condition. (Tr. 90, 92-93.) He also indicated that neither Sweet's syndrome nor serum sickness have any required biomarkers. (Tr. 99-100, 106.) Dr. Tornatore testified: "the bottom line is everyone keeps saying this is a post-vaccination inflammatory event. Whether they use the term 'sweet's syndrome or 'serum sickness' is irrelevant. They're all saying the same thing." (Tr. 144.) Describing petitioner's "weird symptoms," he contended that "you just draw a straight line across and it makes sense." (Tr. 178.) He did, however, acknowledge the importance of petitioner's rash biopsy as a foundation for the alleged diagnosis of Sweet's syndrome, explaining that "there was a lot of clinical judgment that went into it. But clearly it was driven by the skin biopsy." (Tr. 101-02.) Dr. Tornatore deferred to Dr. Jaradeh regarding the question of autonomic neuropathy, but confirmed that his opinion would not change regardless of the presence of autonomic involvement. (Tr. 161-63.)

b. Respondent's Experts

i. Phillip Low, M.D.

Respondent relied in part on the opinion of neurologist Dr. Phillip Low to support his position. (Ex. A.) Dr. Low submitted two reports and also testified during the hearing. He was accepted at hearing without objection as an expert in neurology.[20] (Tr. 216-17.)

Dr. Low's first report was in response to Dr. Jaradeh's above-described letter and was filed before Dr. Tornatore entered the case. Dr. Low described POTS as "a condition characterized by a sustained increase in mean heart rate for greater than 30

[20] Dr. Low is board certified in neurology and clinical neurophysiology (autonomic) and holds a position as Professor of Neurology at the Mayo Clinic in Rochester, Minnesota. (Ex. A, p. 1.) He founded and has headed the Mayo Autonomic Laboratory since 1983. (*Id.*) He has published over 400 pieces in medical journals and 4 books on autonomic diseases. (*Id.*) He developed and validated autonomic function tests that have become the standard testing for autonomic function disorders. (*Id.*) He has published extensively on orthostatic intolerance, postural tachycardia syndrome (POTS), and the autoimmune autonomic neuropathies. (*Id.*)

beats per minute above resting heart rate within 10 minutes of tilt, associated with symptoms of orthostatic intolerance when the person stands up, and clears when the person sits back down." (Ex. A, p. 2.) He explained that because POTS is a condition and not a disease with evidence of tissue injury, the diagnostic criterion is an orthostatic heart rate of greater than 120 bpm. (*Id.*) According to Dr. Low, adult patients who show an orthostatic heart rate increase of 30 or more, but less than 120 bpm, are designated as either mild orthostatic intolerance or mild POTS. (*Id.*) Dr. Low indicated that orthostatic intolerance "refers to symptoms of reduced cerebral perfusion and symptoms of sympathetic activation when a person stands up." (*Id.*) POTS is "a classic example of orthostatic intolerance" where heart rate on standing is excessive due to sympathetic overactivity.[21] (*Id.*) Dr. Low described autoimmune autonomic neuropathy as any number of peripheral neuropathies where the patient's immune mechanisms target autonomic fibers or neurons. (*Id.*) According to Dr. Low, the mechanism of injury is often an antibody directed against autonomic targets. (Ex. A, p. 3.) Dr. Low explained that these types of neuropathies are "characterized by severe loss of function in BP control, control of bladder, bowel, sexual function, or pupils." (*Id.*)

Dr. Low noted that there are several components of Dr. Jaradeh's opinion that are "fully susceptible to proving or disproving." (Ex. A, p. 4.) The standard test for the polyradiculitis diagnosed by Dr. Jaradeh is EMG and nerve conduction study. Petitioner's EMG/nerve conduction results showed no abnormalities, suggesting the diagnosis of polyradiculitis is incorrect. (*Id*.) Additionally, orthostatic hypotension which refers to "a fall of at least 20mm within 3 minutes" during a tilt study. (*Id.*) Petitioner's tilt study showed bp of 128, 114, 110, 103, and 110 at supine, 1, 3, 5, and 10 minutes respectively. (*Id.*) Dr. Low notes that these results are normal and do not demonstrate orthostatic hypotension. (*Id.*) Further, petitioner's heart rates during the tilt test were 71, 85, 85, 91, and 90 at supine, 1, 3, 5, and 10 minutes respectively which illustrates heart rate changes "well below the 30 bpm that is a minimum requirement [for a diagnosis of orthostatic tachycardia]." (*Id*.) In Dr. Low's opinion, Dr. Jaradeh based this diagnosis on a single value from a Finapres[22] recording and suggested that "a single value from the device is highly inaccurate and should be discarded." (*Id.*)

Nor, according to Dr. Low, did Dr. Jaradeh's study reveal any evidence that could support a diagnosis of autonomic neuropathy. Based on the studies, all indices of cardiovagal function and adrenergic function were "completely normal." (Ex. A, p. 4.) Dr. Low explained that "[t]he best indices of adrenergic function are BP recovery time and BP overshoot both of which were completely normal." (*Id.*) Instead, Dr. Low noted, the study provides cogent evidence that petitioner had completely normal autonomic

[21] Dysautonomia without orthostatic tachycardia is a condition manifesting symptoms similar to POTS, but without satisfying the diagnostic heartrate criteria. (Ex. A, p. 3.) He explains that it is not known whether this is a milder form of POTS or something different, but that the condition is known to be dominated by deconditioning which "refers to a condition where an individual, for whatever reasons, becomes inactive for a period of time. This lack of exercise in turn results in lightheadedness, fatigue, and an inability to function." (*Id.*) He notes that, as is often the case with POTS, autonomic perturbances are minimal but psychological factors are often prominent. (*Id.*)

[22] A device used to measure blood pressure continuously. (Ex. A, p. 4.)

function and that Dr. Jaradeh's diagnosis is incorrect. (*Id.*) Dr. Low explained that autoimmune autonomic neuropathy manifests through fixed, dilated pupils, decreased stomach function, bowel and bladder incontinence, and/or orthostatic hypotension. (*Id.*) Because petitioner showed none of these signs, Dr. Low concludes that Dr. Jaradeh's diagnosis is incorrect. (*Id.*)

Dr. Low further stressed that all of petitioner's tests excluded structural disease and therefore, do not support a finding of any injury in this case. (Ex. A, p. 4.) He noted that petitioner's most significant symptoms included head pressure, neck discomfort, fatigues, and dizziness. (*Id.* at p. 5.) Dr. Low suggested that these symptoms are "quite typical of deconditioning" and "by his own description, [] petitioner had changed his lifestyle from being an active exercising young man to one who shunned physical activity," which is behavior that Dr. Low opined commonly leads to deconditioning and the major symptoms of which petitioner complained. (*Id.*)

Dr. Low also submitted a supplemental report on June 15, 2018 in response to Dr. Tornatore. (Ex. E.) Dr. Low explained that neuro-Sweet syndrome is an expansion of Sweet syndrome and cannot be diagnosed if the petitioner did not suffer from Sweet's in the first place. (*Id.*) Dr. Low explained that the two pillars of diagnosis for neuro-Sweet syndrome in petitioner's case would be aseptic meningitis and neuropathy. (*Id.*) He explains that peripheral neuropathy is always associated with findings on EMG and nerve conduction studies. (*Id.*) Because petitioner's EMG, brain MRI, and nerve conduction tests were all normal, Dr. Low concluded that these tests all ruled out neuropathy and radiculopathy. (*Id.*)

Dr. Low also explained that aseptic meningitis was considered briefly due to petitioner's head pressure and neck discomfort in the absence of fever, however, based on petitioner's medical records, "this diagnosis does not seem to have been seriously considered since the condition was mild and since [the] patient was much improved." (Ex. E.) Dr. Low described aseptic meningitis diagnosis as requiring a cerebrospinal fluid sample which is required to show an increase in white cell count, typically lymphocytes. (*Id.*) Because petitioner never received a spinal fluid analysis, the record lacks any evidence necessary to make a diagnosis of aseptic meningitis. (*Id.*) Dr. Low concluded that because petitioner suffered from neither aseptic meningitis nor peripheral neuropathy, the two pillars of diagnosis for neuro-sweet syndrome have not been found, and therefore, Dr. Tornatore's diagnosis is in error. (*Id.*)

During the hearing, Dr. Low stressed that, given the rarity of Sweet's syndrome, the diagnostic criteria is especially important. (Tr. 217.) He opined that petitioner's presentation "just doesn't add up" to Sweet's syndrome. (*Id.*) He noted that petitioner's rash was evanescent, a contrast to the fixed and painful rash with raised plaques seen in Sweet's syndrome. (Tr. 217-18.) He also noted that petitioner's biopsy showed only sparse infiltrate whereas dense infiltrate is required for diagnosis. (Tr. 218-19.) According to Dr. Low, sparse infiltrate is non-specific and comparable to a negative finding. (Tr. 236.) Dr. Low also stressed the complete absence over time of any inflammatory markers in petitioner's blood work as well as suggesting the temporal

pattern of petitioner's symptoms is "all wrong" for neuro-Sweet's syndrome. (Tr. 221, 224.) He also described the continued evolution of petitioner's symptoms as "perplexing." (Tr. 226.)

ii. Michael Girardi, M.D.

On June 11, 2018, respondent filed an expert report from dermatologist Dr. Michael Girardi.[23] (Ex. C.) Dr. Girardi did not testify. Dr. Girardi noted that petitioner made no mention of any rash or skin lesions when he initially complained of an adverse vaccine reaction on August 30, 2012. (*Id.* at 3.) Instead, on September 4, 2012, petitioner noted that he was feeling better following a course of Azithromycin which "is consistent with the diagnosis made of upper respiratory infection and sinusitis." (Ex. C, p. 4.) Additionally, on September 17, 2012, Dr. Bhattacharya noted some small pruritic reddish lesions, which Dr. Girardi explained are "not consistent with Sweet syndrome," but most consistent with hives. (*Id.*) Dr. Girardi further explained that petitioner's transient morning rashes are also inconsistent with Sweet's, and again most consistent with hives. (*Id.*) He noted that petitioner's December 7, 2012 labs show no inflammatory markers, let alone any biomarkers that would support a diagnosis of Sweet's or serum sickness. (*Id.*) In particular, he stressed that petitioner showed normal ESR and CRP levels each time he was tested, and because Sweet's and serum sickness both involve inflammatory responses, petitioner's lack of inflammatory markers is inconsistent with both conditions. (*Id*. at 5.) Dr. Girardi believes that Dr. Braskett incorrectly diagnosed "resolved serum sickness" based on the fact that the lesions petitioner described as occurring between his fingers are inconsistent with serum sickness and "most readily seen in common hand dermatitis/eczema". (*Id.* at 4.) Dr. Girardi indicated that petitioner's "high" tetanus toxoid antibodies is not a significant finding because "the antibody levels seen on the blood test are what would be expected after vaccination or booster vaccination." (*Id.* at 5.)

Dr. Girardi questioned several conclusions drawn by petitioner's treating physicians, opining that the history of petitioner's rashes is "not at all consistent with Sweet's syndrome which typically shows fixed plaques, not a rash that comes and goes . . . ." (Ex. C, p. 6.) Further, he explained that petitioner reported no annular, serpiginous, urticarial, multiforme, petechial, or purpuric lesions that may be seen in a serum sickness or serum sickness-like syndrome which leads him to conclude that petitioner's skin lesions "are neither typical of nor consistent with Sweet's or serum-sickness." (*Id.*)

Dr. Girardi believes that petitioner's original symptoms were due to sinusitis and hives. (*Id.*) This is based on the fact that petitioner's rashes were transient instead of permanent, that petitioner had a history of developing hives after certain medications,

[23] Dr. Girardi is Professor and Vice Chair of Dermatology for the Yale School of Medicine. (Ex. C, p. 1.) He has also served as Residency Director for Dermatology at Yale for over 15 years. (*Id.*) Dr. Girardi runs a research laboratory focused on inflammatory immune reactions and their interaction with the skin. (*Id.*) He is an elected member of the American Society of Clinical Investigation and has published over 150 pieces of medical literature on skin biology. (*Id.* at 2.)

and importantly, that petitioner described rashes on his hands prior to his vaccinations. (*Id*.) Dr. Girardi explained that petitioner's head pressure, sinus congestion, and pharyngeal erythema are all "very consistent with an upper respiratory infection and sinusitis." (Ex. C, p. 6.) Dr. Girardi further supported this conclusion by noting that petitioner responded well to antibiotics with "substantial alleviation of his sinusitis symptoms." (*Id.* at 7.) He explained that hives is a migratory rash where specific lesions only last for a matter of hours and that forming hives in response to antibiotics is not a rare phenomenon. (*Id.*) Based on the foregoing, Dr. Girardi concluded that petitioner likely developed hives in response to either the antibiotics he was prescribed, or his sinusitis. (*Id.*)

Dr. Girardi also contended that "there is no evidence that [petitioner] has, or ever had, Sweet syndrome." (*Id.*) He cited the von den Driesch report used by petitioner's expert to explain the diagnostic criteria for Sweet's syndrome as presenting on the skin "multiple, painful, sharply demarcated, raised erythematous plaques on the face, neck, upper chest, back, and extremities that may show a mamillated appearance with pseudovesiculation, pseudopustulation and pustules [that are] red to blue-red in color." (Ex. C, p. 7 (citing von den Driesch, *supra,* at Ex. 34).) Dr. Girardi contrasted this description to the rashes that petitioner experienced which were described as "intermittent . . . flat, red, speckled . . . faint in quality . . . [and appearing] only in the morning [lasting] less than an hour." (*Id.*) Dr. Girardi explained that petitioner's medical records never mention pseudovesiculated or vesiculated, painful, raised red to blue-red plaques that are characteristic of Sweet's. (*Id.*) Nor did petitioner experience any associated symptoms such as enlarged lymph nodes, erythema nodosum lesions, or conjunctivitis. (*Id.*) Based on the diagnostic criterion, as well as petitioner's lack of inflammatory markers, Dr. Girardi concluded that petitioner has "never come close to satisfying the criteria for a diagnosis of Sweet syndrome." (*Id.*) Instead, Dr. Girardi opined that petitioner's rash is likely the result of chronic urticaria.[24] (Ex. C, p. 9.)

Dr. Girardi also opined that petitioner's diagnosis of neutrophilic dermatosis is highly speculative because it is based on a generalized biopsy finding of "sparse perivascular infiltrate with neutrophils." (Ex. C, p. 8.) According to Dr. Girardi, this finding is inconsistent with Sweet's syndrome, because Sweet's is accompanied by "an infiltrate consisting of mononuclear cells and numerous neutrophils with leukocytoclasis, a marked vasodilation and swelling of the vascular endothelium with moderate erythrocyte extravasation, and prominent edema of the upper corium frequently leading to the formation of vesicles or bullae and inflammatory cells that exhibit a bandlike infiltration throughout the papillary dermis." (*Id.*) Because petitioner's biopsy only showed "sparse perivascular infiltrate with neutrophils" and none of the more specific findings listed in the diagnostic criteria for Sweet's syndrome, Dr. Girardi opined that

[24] Dr. Girardi cited a study which specifically notes that Sweet's syndrome resolves once the inciting agent is removed from the host. (Ex. C, p. 9 (citing Caroline A. Nelson et al., *Neutrophilic dermatoses, Part I. Pathogenesis, Sweet syndrome, neutrophilic eccrine hidradenitis, and Bechet's disease*, 79 J. AM. ACAD. OF DERMATOLOGY 987 (2018) (Ex. C. Tab 1).) This study found that reports of Sweet's syndrome in association with certain vaccines are rare, and none of the vaccines linked to Sweet's were of the type that petitioner received. (*Id.*)

there is no evidence to find that petitioner was in fact suffering from Sweet's syndrome. (*Id.*)

Dr. Girardi's final discussion focused on petitioner's diagnosis of serum sickness induced neuropathy or myopathy. He noted that petitioner has a documented history of muscle fasciculations and autonomic dysfunction such as his orthostatic hypotension. (*Id.*) He indicated, however, that "there is no plausible medical or laboratory evidence that these [symptoms] are due to inflammation, such as those [that] might be caused by a serum sickness or neutrophilic syndrome trigged by an adverse vaccination reaction." (*Id.*) He explained that if petitioner did suffer from a systemic serum sickness or serum sickness-induced myopathy or neuropathy, he would have likely shown increased muscle enzyme levels, abnormal nerve conduction, brain abnormalities, and/or elevated inflammatory markers. (Ex. C, p. 8.) Here, however, petitioner showed none of these things, his muscle enzyme levels were normal, his nerve conductions studies were normal, his brain MRIs were normal, and his labs revealed no inflammatory markers. (*Id.*) Further, because petitioner's muscle fasciculations were not associated with any pain or numbness, Dr. Girardi believes that petitioner's fasciculations were likely the result of "benign fasciculation syndrome." (*Id.*)

Dr. Girardi explained that he is unaware of any credible reports linking Tetanus or Hepatitis A vaccines to neuro-Sweet's syndrome, serum sickness, or serum sickness-like reactions.[25] (Ex. C, p. 9.) He explained that serum sickness and serum sickness-like reactions "require persistent and high levels of antigen that co-precipitate as immune complexes with persistent and high levels of antibodies." (*Id.*) Thus, high levels of antibodies alone are not evidence of serum sickness because such a diagnosis would require an additional finding of persistent and high levels of antigen, which is not evidenced in petitioner's medical records. (*Id.*) Dr. Girardi ultimately concluded that "there is absolutely no medical history, clinical, dermatologic, histologic, or laboratory evidence in [petitioner's medical records] to support the diagnosis of Sweet syndrome, neuro-Sweet syndrome, serum sickness, or serum sickness-like eruption." (*Id.*)

iii. You-Wen He, M.D., Ph.D.

Respondent filed his final expert report by immunologist Dr. You-Wen He on October 7, 2019.[26] (Ex. F.) Dr. He also testified during the hearing at which he was accepted without objection as an expert in immunology. (Tr. 185.)

[25] In his report Dr. Girardi noted: "I am not aware of any credible reports of the vaccines in question (DTAP, HepA) leading to any type neuro-Sweet syndrome or serum sickness or serum sickness-like reactions." (Ex. C, p. 9.) Dr. Girardi's reference to the "vaccines in question" suggests his reference to "DTAP" vaccines was likely a typographical error.

[26] Dr. He has been a Professor of Immunology in the Department of Immunology at Duke University Medical Center since 1986. (Ex. F, p. 1.) His research areas include innate and adaptive viral and bacterial immunity. (*Id.*) He has directed research on human immune responses to viral infections including influenza, HIV, HBV, and HCV. (*Id.*) He has been the Director of Immunology of Human Diseases at Duke university for the past five years and is the current co-Principal Investigator for four clinical trials focusing on cancer immunotherapy. (*Id.*) He has served as a reviewer for over 20 different scientific journals and has published extensively immunology. (Ex. G, pp. 9-17.)

Dr. He primarily discussed whether petitioner's condition can be explained by serum sickness. (Ex. F, p. 3.) He defines serum sickness as a "type III immune complex-mediated hypersensitivity disease" caused by immunization of heterologous serum proteins and subsequent illness through the formation of immune complexes. (*Id.*) Dr. He explained that once a patient is immunized with a protein antigen, "antibody IgM and IgG develop beginning 1 week later" and that "persistence of high amount of antigen in the host" leads to antigen-antibody complex formation. (*Id.*) These immune complexes in turn "may deposit in tissues and activate complement system[s]." (*Id.*) Further, "complement activation causes the release of complement fragments C3a and C5a, which causes mast cell degranulation, histamine release, vasodilation, enhanced vascular permeability, the development of urticarial lesions, and neutrophil recruitment." (*Id.*) Dr. He noted that "studies also suggest complement-independent mechanisms are involved in serum sickness." (Ex. F, p. 3.) Serum sickness-like reactions (SSLRs) on the other hand, "are clinical reactions to a variety of drugs that resemble serum sickness" and can occur following either infection or vaccination. (*Id.*)

According to Dr. He, "the most common symptoms of serum sickness are dermatitis (rash), fever, polyarthralgia, or polyarthritis that usually begin 1-2 weeks after exposure to the agent." (*Id.* at 3-4.) Dr. He noted that almost all serum sickness patients develop a fever and a pruritic rash lasting between a few days to two weeks. (*Id.* at 4.) Further, Dr. He explained, around two-thirds of serum sickness patients develop arthralgias with pain in their knees, wrists, ankles, shoulders, and jaw. (*Id.*) When diagnosing serum sickness, Dr. He explained that lab results usually reveal systemic changes including neutropenia, development of reactive plasmacytoid lymphocytes, and elevated levels of ESR and CRP. (*Id.*) Dr. He also notes that serum sickness usually resolves within 2 weeks of clearance or removal of the causative agent but that in "unusual cases, symptoms may persist for 2-3 months if the causative agent has been administered as a depot or sustained release form." (Ex. F, p. 4.)

According to Dr. He, Dr. Tornatore's reliance on the Apisarnthanarak study finding a 3% incidence rate of serum sickness following a flu vaccination in Thai health professionals is "quite unusual as there are no other reports that support this level of incidence from any other countries including the United States." (*Id.*) "In fact," Dr. He continued, "serum sickness or SSLRs were rarely reported after any vaccination. As the authors indicated, the one-time observed 3% incidence in Thailand could be due to the fact that the specific batch of vaccine was manufactured locally." (*Id.*) Dr. He explained that "since 1991, [over 800 million] doses of trivalent inactivated virus vaccine have been distributed in the United States. As of December 2008, only 45 unconfounded reports . . . of possible serum sickness after receipt of a trivalent inactivated virus vaccine were submitted to the VAERS." (*Id.*) Dr. He further explained that these 45 case reports fail to establish any link between the flu vaccine and serum sickness and therefore, even adding these cases to Dr. Tornatore's limited evidence, there is still no way to reasonably link petitioner's vaccinations to serum sickness. (*Id.*)

Dr. He does not believe that petitioner suffered from serum sickness or a SSLR for four reasons. First, petitioner did not have any fever, and "[v]irtually all serum sickness patients develop fever that is above 101.3 degrees Fahrenheit as the immune complex-induced reaction triggers an inflammatory response." (Ex. F, p. 5.) Second, petitioner did not develop rash or any skin lesions by his August 30, 2012 exam, which would take his condition outside the typical timeframe by which such symptoms would arise following vaccination. Instead, petitioner's rash developed after taking other medications. (*Id.*) Additionally, petitioner's lab testing consistently showed normal levels of inflammatory biomarkers. (*Id.*) Finally, petitioner's persistent symptoms are inconsistent with the self-limiting nature of serum sickness and SSLRs. (*Id.*) In other words, because serum sickness symptoms resolve once the antigens are cleared from the host body, petitioner should have not continued to experience symptoms if he was in fact suffering from serum sickness. (*Id.*) Importantly, Dr. He explained, a PUBMED search found no reported cases of serum sickness associated with the Hepatitis A or Td vaccines. (*Id.*)

Dr. He also questioned whether petitioner experienced Sweet's syndrome due to auto-inflammation as Dr. Tornatore proposes. According to Dr. He, it is unlikely that petitioner experienced any autoinflammation or autoinflammatory disease regardless of his diagnosis because such diseases are "characterized by recurrent inflammatory episodes with heterogenous symptoms that are frequently associated with fever." (Ex. F, p. 5.) A second prominent feature of these diseases is an increase in acute-phase reactants such as CRP. (*Id.*) Because petitioner "had neither fever nor elevated acute-phase reactant CRP," Dr. He concludes that petitioner did not experience any autoinflammation, and therefore, did not experience an autoinflammatory disease such as Sweet's. (*Id.*) Based on the above, Dr. He concludes that petitioner likely did not experience serum sickness, nor sweet's syndrome.

During the hearing, Dr. He testified in accordance with his report and also provided additional testimony regarding petitioner's skin biopsy. In contrast to a finding of "dense" neutrophil infiltrate (which would be "very significant"), "sparse" neutrophil infiltrate should be interpreted as equivocal and nonspecific. (Tr. 203, 205-06.) He explained that when taking a tissue sample "it's actually almost impossible to have zero hematopoietic cells, immune cell infiltration" and opined that petitioner's skin biopsy is not diagnostic of Sweet's syndrome. (Tr. 191, 203.)

V. Discussion

As the above discussed history shows, petitioner had a prolonged course of evolving symptoms and underwent a years-long search for a unifying diagnosis to little avail. His physicians were clearly willing to entertain the possibility that petitioner suffered some kind of vaccine reaction. However, many diagnoses were proposed, debated, and ultimately either set aside or never confirmed or pursued. None of the possible unifying diagnoses proposed by petitioner's treating physicians enjoyed broad support among his treatment teams.

In the face of that history, petitioner's expert in this case, Dr. Tornatore, suggests that two proposed diagnoses from among those considered by the treating physicians can be substantiated – a neurologic form of Sweet's syndrome and a serum sickness-like reaction. He further opines that both of these conditions were caused by the vaccinations at issue in this case. Additionally, during the hearing, Dr. Tornatore suggested that there is sufficient suspicion of an inflammatory condition among petitioner's treating physicians to support vaccine-causation regardless of diagnosis. Respondent and his three experts dispute all of these contentions. Additionally, respondent contends petitioner's failure to substantiate his correct diagnosis means a causation-in-fact analysis under the *Althen* test is not possible. (ECF No. 103, pp. 21-22.) In order to resolve these differences, two different analyses are required.

Petitioner bears the burden of proving his injury was caused-in-fact pursuant to the *Althen* test. However, where diagnosis is in dispute, the Federal Circuit has found it appropriate for special masters to determine which diagnosis is best supported by the evidence in the record before applying the *Althen* test "so that the special master could subsequently determine causation relative to the injury." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). The Court explained that because each prong of the *Althen* test is decided relative to the injury, identifying the injury is a prerequisite to the analysis. *Id*. And, in any event, a petitioner must prove by a preponderance of the evidence the factual circumstances surrounding his claim. § 300aa–13(a)(1)(A). Importantly, however, "[t]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)).

Balancing these considerations, a threshold analysis is required to determine whether there is preponderant evidence that petitioner suffered either of the two specific conditions Dr. Tornatore proposes as explanations for petitioner's clinical history (Sweet's syndrome and/or serum sickness). However, even finding that there is not, a remaining question raised by Dr. Tornatore's testimony is whether, in the absence of any reliance on those specific diagnoses, there is nonetheless sufficient basis for the suspicion of an unspecified inflammatory reaction to preponderantly establish causation-in-fact pursuant to the *Althen* test. The analysis below concludes that there is not.

a. Diagnosis

i. Sweet's Syndrome or Neuro-Sweet's Syndrome

Sweet's syndrome, also known as acute febrile neutrophilic dermatosis, is an autoimmune/autoinflammatory condition of the skin, usually occurring after a nonspecific infection of the respiratory or gastrointestinal tract that results in "[r]aised erythematous plaques with pseudo-blistering and occasionally pustules . . . on the face,

neck, chest, and extremities accompanied, by fever and general malaise." (Ex. 32, p. 5.) It is one of a number of dermatologic conditions known has neutrophilic dermatoses. Sweet's syndrome may also involve more vascular bodily systems and involve the eyes, joints, and oral mucosa, as well as the lungs, liver, kidneys, and rarely in the case of neuro-Sweet's syndrome, the central nervous system, most often causing aseptic meningitis or encephalitis. (*Id.* at 5-6; *see also* Tr. at 92-94.)

In this case, of all the many specialists petitioner visited throughout the course of his years-long search for a diagnosis, including multiple dermatologists, only the team of Drs. Bhutani and Berger even suggested the possibility of Sweet's syndrome. This occurred more than two years after the vaccinations at issue. (Ex. 23, pp. 1-2.) The suspicion of Sweet's syndrome expressed by Drs. Bhutani and Berger was based in significant part on the skin biopsy results interpreted by Dr. Pincus. However, although Dr. Pincus included neutrophilic dermatosis in a differential diagnosis, she also indicated that the neutrophil infiltration seen on biopsy was only "sparse" and further indicated that the eruption biopsied could also be explained by conventional urticaria. (Ex. 23, p. 16.) Ultimately, despite suggesting Sweet's syndrome as a possible diagnosis, Drs. Bhutani and Berger indicated that petitioner's condition was actually best characterized as Neutrophilic Dermatosis, NOS (not otherwise specified) and indicated the need to wait to see if petitioner's condition develops to be "more characteristic" of a defined condition from among a wide differential diagnosis while "keeping our minds open as to possible etiopathogenesis." (Ex. 23, p. 2.) Petitioner never had any follow up or treatment based on the suspicion of Sweet's syndrome, neuro-Sweet's syndrome, or neutrophilic dermatosis more generally. (Ex. 23, p. 2; Tr. 47.) Thus, although Sweet's syndrome garnered some mention by some of petitioner's treating physicians, petitioner's medical records considered as a whole do not, without more, preponderantly establish that petitioner was diagnosed as suffering Sweet's syndrome by any of his treating physicians. Those who considered it did not move beyond suspicion.

Nonetheless, petitioner suggests there is adequate evidence of record to support Dr. Tornatore's additional expert opinion that such a diagnosis can explain petitioner's presentation. The most obvious issue with Dr. Tornatore's opinion is that petitioner's own rash is not consistent with the known dermatologic presentation of Sweet's syndrome and his biopsy is inadequate to diagnosis neutrophilic dermatosis more generally. This issue alone is dispositive. Additionally, however, respondent's experts also raise several other reasons for doubting that petitioner's overall presentation is consistent with either Sweet's syndrome specifically or with the category of neutrophilic dermatoses more generally. Finally, petitioner's initial presentation of headache is not sufficient to establish the presence of the aseptic meningitis supporting the neuro-Sweet's syndrome variant, a point that further contributed to Dr. Tornatore's overall diagnostic assessment.

1. Petitioner's rashes

As a dermatosis, Sweet's syndrome is first and foremost an immune response that manifests as a dermatologic condition. (*E.g.*, von den Drisech, *supra*, at Ex. 34, p. 535.) Respondent's experts are persuasive in explaining that the presence of characteristic painful skin plaques with dense neutrophil infiltration is critical to diagnosis. (Tr. 201-02, 217-18, 221-22, 232-33; Ex. C, p. 7; *see also* Nelson et al., *supra,* at Ex. C, Tab 1, p. 14).) Petitioner's reliance materials likewise confirm that this presentation is generally accepted as the major diagnostic criteria for Sweet's syndrome. (von den Driesch, *supra*, at Ex. 34, pp. 535, 544 (Table V).) Without the characteristic dermatologic presentation, there is no basis to suspect Sweet's syndrome as any explanation for petitioner's broader multi-system presentation.

Throughout the medical records, petitioner's rashes are variously described as follows: transient and periodic (Ex. 2, p. 251; Ex. 13, p. 7; Ex. 14, p. 17), patchy and erythematous (*i.e*. red) (Ex. 2, p. 225; Ex. 13, p. 7), speckled or splotchy (Ex. 2, p. 234; Ex. 14, p. 17), pruritic (*i.e*. itchy) (Ex. 7, p. 10; Ex. 23, p. 13), and maculopapular (Ex. 14, p. 18). With the exception of the one rash that was biopsied, petitioner testified that his rashes were fleeting, by which he meant they lasted for only minutes to hours. (Tr. 24-26.) There is no indication from either the medical records or petitioner's testimony that his rashes were painful. All of this is in contrast to the expected presentation for Sweet's syndrome. Whereas the rashes seen in Sweet's syndrome are fixed, clearly demarcated, painful, and with skin plaques, petitioner's rashes had none of these features in terms of either appearance or pattern of manifestation. Additionally, petitioner's rashes were also described as pruritic, which is an added characteristic not consistent with Sweet's syndrome. (*See, e.g.* von den Driesch, *supra*, at Ex. 34, pp. 537-38 (explaining that multiple sharply demarcated raised erythematous plaques that are burning and painful, but not pruritic, are considered a "hallmark" of Sweet's syndrome).) Moreover, petitioner has provided photographs of his rashes. Comparison between these photographs and the photographs of Sweet syndrome rashes contained in the medical literature filed in this case shows, even at a glance, that petitioner's rashes are in stark contrast to the rashes depicted among Sweet's syndrome patients. Dr. Tornatore agreed. (Tr. 120-22; *Compare* Ex. 51, *and e.g.*, von den Driesch, *supra,* at Ex. 34, p. 538 (fig. 3), Carpentier et al., *supra,* at Ex. 37, p. 221 (Fig. 1), Jovanovic et al., *supra,* at Ex. 38, p. 368 (Fig. 1), Wolf et al., *supra,* at Ex. 39, p. 1 (Fig. 1), Pendrosa et al., *supra,* at Ex. 40, p. 261 (Fig. 1), Hisanaga et al., *supra,* at Ex. 41, p. 1757 (Fig. 1).)

Nonetheless, Dr. Tornatore stresses that petitioner's biopsied rash did demonstrate neutrophil infiltration. (Tr. 83-84, 101-02, 120-26.) Here too, however, petitioner's own rash is inconsistent with the diagnostic standard for the condition at issue. Petitioner's own biopsy showed only "sparse" neutrophil infiltrate. (Ex. 23, p. 5.) In contrast, "dense" neutrophil infiltrate on histopathology was a part of the initial presentation documented by Dr. Douglas Sweet when he coined the term "acute febrile neutrophilic dermatosis" to describe this condition. (*See* Nelson et al., *supra*, at Ex. C, Tab 1, p. 13.) Dense infiltrate has also been specified as part of the subsequently developed diagnostic criteria. (*See* Drago et al., *supra*, at Ex. 42, p. 34 (Table 1); *accord* Maddox & Motley, *supra,* at Ex. 36, p. 810 (case report indicating that difficult diagnosis

of Sweet's syndrome "hinged" on histopathology showing, *inter alia*, "intense neutrophilic infiltrate"); Wolf, *supra*, at Ex. 39, p. 1 (case report noting dense infiltrate on histopathology as one of two major criteria offering "clues to the diagnosis").) When neutrophil infiltrate is less dense, the differential diagnosis should be widened. (von den Driesch, *supra*, at Ex. 34, pp. 539-44.) In fact, Dr. Tornatore concedes that sparse neutrophil infiltrate is not necessarily diagnostic of Sweet's syndrome in particular, even while maintaining that it should be viewed as evidence of inflammation more broadly.[27] (Tr. 121.)

With regard to that broader assertion, however, respondent's experts also persuasively contend that the interpretation of the biopsy as including only "sparse" neutrophil infiltrate should in itself be interpreted with caution as non-specific, if not rejected as a negative or equivocal finding. (Tr. 191, 203, 205-06, 218-19, 236; Ex. C, p. 8.) Specifically, Dr. Low testified that the difference between "sparse" and "dense" neutrophil infiltration is "night and day." (Tr. 218-19.) He indicated that a finding of sparse neutrophil infiltrate is a "minor non-specific" abnormality. (*Id*.) Consistent with Dr. Pincus's dermatopathology report, Dr. Low indicated that anyone who scratches a urticarial rash could have sparse neutrophil infiltrate.[28] (*Id*.) On further questioning, Dr. Low even went as far as to suggest the sparse infiltrate could be interpreted as a negative finding. (Tr. 236.) Dr. He likewise testified that sparse infiltrate is a non-specific finding. (Tr. 191.) He indicated that whereas "dense" infiltration would be "very significant," a finding of "sparse" infiltration is equivocal and may indicate no abnormality at all. (Tr. 205-06.) He explained that tissue section contamination is always a possibility and "it's actually almost impossible to have zero hematopoietic cells, immune cell infiltration." (Tr. 203, 205-06.) Respondent's expert in dermatology, Dr. Girardi, also indicated in his report that the finding of sparse infiltrate is non-specific. (Ex. C, p. 8.) Further, Dr. Girardi specifically opines that petitioner's biopsy result is inadequate to diagnose even a broader neutrophilic dermatosis, calling such a suggestion "speculative" and instead opining that petitioner suffered hives. (Ex. C, pp. 6-8.) And again, even if Dr. Pincus was open to the possibility of neutrophilic dermatosis based on reported clinical history, Dr. Girardi's opinion that the result should be interpreted as

[27] Specifically, Dr. Tornatore testified: "But I think the important thing is that here we have a rash, and we can call it whatever we want. We can call it hives. We can call it atypical Sweet's. We can call it not Sweet's. He – it's persistent. He did not have it prior to the vaccination. He had a serum sickness-like reaction, ergo, we can say, well is it related or is it not? Well, of course, that's that constellation that, you know, the going from one thing to another. So we may not call it, you know, a classic Sweet's syndrome, but it did have neutrophils in it and so it fits in that category of Sweet's-like syndromes or, you know, those innate inflammatory dermatologic issues." (Tr. 121.)

[28] In her report, Dr. Pincus limited the top-line diagnostic finding to "sparse" perivascular infiltrate with neutrophils without indicating a diagnosis of neutrophilic dermatosis. Although she discussed the possibility of an unspecified neutrophilic dermatosis in her further analysis, she also specified both conventional and neutrophilic urticaria on equal footing as possible considerations. (Ex. 23, p. 16.) Dr. Pincus's inclusion of both conventional and neutrophilic urticaria in her report indicates that based on her own review of the pathology she could not necessarily distinguish petitioner's biopsy from conventional hives. This is consistent with respondent's experts' shared opinion that the finding is nonspecific and consistent with ordinary or "conventional" hives. (Ex. 23, p. 16; Tr. 218-19; Ex. C, pp. 7-8.) On the whole, Dr. Pincus's report is equivocal with regard to the clinical significance of the underlying pathology.

non-specific even as to the broader category of neutrophilic dermatoses is consistent with the dermatopathology report findings when the report is read as a whole. (Ex. 23, p. 16; *see* n. 28, *supra.*)

Although Dr. Tornatore sought to disregard the distinction between sparse and dense neutrophil infiltration (Tr. 83-84, 113-15), he is less well qualified to make that determination.[29] Moreover, Dr. Tornatore presented a far less nuanced view of petitioner's skin rashes. His testimony regarding the biopsy result was never more specific than to assert that the presence of any degree of neutrophil infiltrate indicates inflammation "period" while also agreeing petitioner's own rashes were potentially consistent with hives.[30] (Tr. 83, 114-15, 122-24.) He sought to at least some degree to defer to the interpretation of the dermatologists. (Tr. 150-51.) However, both respondent's dermatology expert and Dr. Pincus indicate that conventional hives are a possible explanation of petitioner's biopsy result, inclusive of the finding of some possible evidence of minimal inflammation.

Based on all of the above, there is not preponderant evidence that petitioner's dermatologic presentation fits either the diagnosis of Sweet's syndrome specifically or even neutrophilic dermatosis more generally. This finding alone is dispositive as to the question of whether petitioner had Sweet's syndrome. Nonetheless, it is not the only reason for doubting the proposed diagnosis.

2. Overall clinical history

Even setting aside the rashes and skin biopsy, the Sweet's syndrome diagnosis still remains an unsatisfying explanation for petitioner's overall clinical history. Petitioner's clinical history stands in significant contrast to Sweet's syndrome in

[29] Dr. Girardi's qualification as a dermatologist likely leaves him best positioned to interpret skin biopsy results in terms of overall clinical significance. Additionally, Dr. He's qualification as an immunologist qualifies him to speak to the significance of neutrophil counts specifically. Dr. Low and Dr. Tornatore are both neurologists and therefore comparatively less qualified to speak to the specifics of this biopsy result. Dr. Low does additionally purport, however, to have added familiarity with skin biopsies due to his specific work in the area of autonomic dysfunction. Skin biopsies are an important diagnostic tool for dysautonomia. Nonetheless, it is not clear that this experience would necessarily carry over to interpreting neutrophil infiltration specifically. Thus, Drs. Girardi's and He's opinions are the most valuable on this point with Drs. Low and Tornatore being closer to being on equal footing with one another.

[30] An important further point confirmed during the hearing is that the medical records and Dr. Pincus's dermatopathology report are such that only Dr. Pincus had access to the pathology imaging underlying her conclusion. (Tr. 123-26.) The experts and other treating physicians must necessarily rely on Dr. Pincus's interpretation of the infiltrate as "sparse" with no opportunity to reach any separate assessment. Thus, Dr. Tornatore's specific suggestion that it would be "quibbling" to say the infiltrate is not "dense" is unpersuasive. (Tr. 124.) Dr. Tornatore has no basis for disputing Dr. Pincus's specific finding that the infiltrate is "sparse." This also has a bearing on the weight that can be placed on Drs. Bhutani's and Berger's subsequent invocation of Sweet's syndrome. There is no basis for concluding that Drs. Bhutani and Berger based their assessment on any differing interpretation regarding the degree of neutrophil infiltration shown by the underlying imaging.

important ways. Petitioner had no fever at or around the onset of his alleged vaccine reaction. (Tr. 126) Fever at onset is a hallmark of the condition as it is "acute *febrile* neutrophilic dermatosis." (von den Driesch at Ex. 34, supra, pp. 535, 544 (Table V).) Moreover, despite having bloodwork completed on numerous occasions throughout his illness, including on August 30, 2012 (Ex. 2, p. 126), which would have been during or close in time to the alleged acute phase of his condition, petitioner's lab results were consistently within normal limits vis-à-vis markers that would indicate systemic inflammation. Even by Dr. Tornatore's own description, Sweet's syndrome is a systemic inflammatory condition. (Tr. 82-83, 92.) This suggests that one should expect elevated inflammatory markers. (Tr. 219-20, 231.) These points, along with petitioner's evolving symptomology, contributed to respondent's experts' opinion that petitioner did *not* have Sweet's syndrome or any form of neutrophilic dermatosis. (Tr. 217, 226.) In short, especially when combined with the equivocal skin biopsy, petitioner's history is largely lacking for any evidence of a systemic inflammatory immune response.

Dr. Tornatore stresses that in real world practice, all medical conditions present as a spectrum. Generally, it is not necessary for a patient to have all the signs and symptoms of a given condition to be properly diagnosed as having that condition. (Tr. 90-93, 169-74.) Moreover, he separately asserts that each of these factors need not be present in this case. He suggests that fever is not ultimately important to his opinion in this case. (Tr. 126, 156.)[31] He suggests that elevated inflammatory markers do not always correlate to symptoms and that there is no pathognomonic marker for Sweet's syndrome. (Tr. 99-100, 153-55.) And he disputes that Sweet's syndrome would be limited or self-resolving in the absence of treatment. (Tr. 130-31.) (He also opines that the presence of aseptic meningitis is evidence of inflammation (Tr. 85, 87, 93); however, this is discussed separately below.)

Dr. Tornatore is correct to the limited extent that these factors relate to minor rather than major diagnostic criteria for Sweet's syndrome. (von den Driesch, *supra*, at Ex. 34, p. 544 (Table V).) Thus, they are not *all* necessary for diagnosis. Lacking from Dr. Tornatore's opinion, however, is any acknowledgement of the cumulative significance of these variances. For example, the Sweet's syndrome diagnostic criteria included in Dr. Tornatore's reliance material require the presence of two major criteria accompanied by two of four minor criteria. The two major criteria are (1) the presence of characteristic rashes with (2) biopsy results inclusive of predominant neutrophil infiltration. (*Id*.) As discussed in the preceding section, neither of these major criteria is present in this case. The minor criteria include (1) a preceding infection or vaccination or associated pre-existing condition, (2) periods of malaise and fever, (3) elevated laboratory values at onset for either ESR, CRP, neutrophils, or leukocytes, and (4) excellent response to treatment with systemic corticosteroids or potassium iodide. (*Id*.) Given his lack of fever, normal bloodwork, lack of treatment, and overall medical history,

[31] Dr. Tornatore principally discussed fever in the context of serum sickness and aseptic meningitis rather than specifically in the context of diagnosing Sweet's syndrome; however, it is clear from his testimony that he felt Sweet syndrome was present regardless of his acknowledgement that there was no fever in this case. (Tr. 126.)

literally the only diagnostic criterion that petitioner has demonstrated is that he was previously vaccinated.

Even if other of petitioner's symptoms overlap with known sequela of Sweet's syndrome, petitioner has none of the diagnostic or characteristic features of Sweet's syndrome. In seeking to take the "50,000 foot view" of petitioner's condition, Dr. Tornatore has failed to demonstrate that he has adequately grappled with the specific details of petitioner's own complicated medical history. In short, he has not shown that his diagnostic assessment of Sweet's syndrome was reliably reached in this case. (*See, e.g.,* Tr. 232 (Dr. Low explaining "there is a spectrum of disorders, but the spectrum is limited; otherwise you become a very sloppy physician.")

3. Aseptic meningitis and neuro-Sweet's syndrome

Dr. Tornatore also based in his opinion in part on his assessment that petitioner's initial headache presentation was diagnosed as aseptic meningitis, which he suggested shows neurologic manifestations of the condition temporally proximate to vaccination. (Ex. 32, p. 6.) He also relied on this aseptic meningitis diagnosis as contributing to the Sweet's syndrome diagnosis by pointing specifically to the neuro-Sweet's syndrome variant. (Tr. 93-96, 147.) Without preponderant evidence that petitioner had Sweet's syndrome in any form, it is not necessary to examine whether he had the specific neuro-Sweet's syndrome variant identified by Dr. Tornatore. However, in the interest of completeness I briefly note that Dr. Tornatore also is not persuasive on this point.

First, Dr. Bhattacharya's records better reflect a suspicion of aseptic meningitis rather than a diagnosis. He initially recorded a "possible" aseptic meningitis. (Ex. 7, p. 18.) He later recorded equivocally during a follow up that petitioner experienced "[a]n episode of symptoms suggestive of aseptic meningitis . . ." but also indicated suspicion of a primary neurologic condition was low. (*Id*. at 10.) During a third visit, after petitioner complained of continuing headaches "off and on" with head pressure especially along the right temple, Dr. Bhattacharya assessed right trigeminal cephalgia and recommended an MRI with attention to the right trigeminal nerve.[32] (*Id*. at 3-6.) (*Compare* Ex. 7, pp. 6, *and* 18.) In that regard, Dr. Low stressed that petitioner's complaints of headache and jaw pain were nonspecific, and his physical exam indicated no signs of meningismus. (Tr. 223-24.) Moreover, Dr. Bhattacharya never ordered a spinal tap which both Drs. Tornatore and Low agree is necessary to confirm meningitis.[33] (Tr. 155-58, 227-28.) Additionally, there was no evidence of meningitis

[32] To be clear, the experts disagree as to the meaning of the trigeminal cephalgia assessment. Dr. Tornatore suggests that it is merely descriptive of the location of petitioner's symptoms rather than constituting any separate diagnosis. (Tr. 158-61.) Dr. Low explains, however, that it is a type of migraine. (Tr. 234.) He opines the assessment of trigeminal cephalgia indicates Dr. Bhattacharya had moved on from the initial suspicion of meningitis. (*Id*.)

[33] Dr. Tornatore stressed that meningitis is largely a clinical diagnosis confirmed by spinal tap and that physicians do not use the term lightly. (Tr. 155-58.) Dr. Low, however, stressed that when there is a suspicion of meningitis, it is very important to get the spinal tap confirmation, because clinical evaluation alone cannot tell whether the meningitis is aseptic or bacterial, the latter of which is very serious. (Tr. 227-

when petitioner had his MRI.[34] (Tr. 226-27.) In fact, petitioner himself testified that Dr. Bhattacharya provided no definitive diagnosis. (Tr. 19-20.)

In any event, Dr. Tornatore's opinion is in itself equivocal on this point. Although he relies on aseptic meningitis as being the most common neurologic presentation for neuro-Sweet's syndrome (Tr. 93-94, 147), he also suggested that Dr. Bhattacharya's alternative suggestion of a vaccine reaction confirms he felt an inflammatory process was present regardless of specific diagnosis (Tr. 143-44). Dr. Tornatore's opinion is hampered by the fact that in seeking to hedge his opinion he alternatively opines that petitioner's headache presentation may be a part of the serum sickness presentation he opines was also present. (Tr. 136-37.) This underscores the uncertainty regarding the potential aseptic meningitis diagnosis. Also important, if petitioner did have aseptic meningitis *in advance of* other manifestations of Sweet's syndrome, this would be a very unusual presentation of the neuro-Sweet's syndrome. (Tr. 224.) When pressed on this specific point, Dr. Tornatore returned to contending that the manifestations of petitioner's purported Sweet's syndrome and serum sickness cannot really be teased apart. (Tr. 145-46.) While Dr. Tornatore's suggestion of aseptic meningitis is not wholly without support in the medical records, Dr. Low was more persuasive in opining that "we have no evidence that this patient ever had anything strongly suggestive of aseptic meningitis." (Tr. 225.)

ii. Serum Sickness or Serum Sickness-like Reaction

According to Dr. Tornatore, serum sickness is a short-term hypersensitivity reaction to foreign antigens causing fever, polyarthritis, polyarthralgia, and/or rash. (Ex. 32, p. 6) (citing Ponvert & Scheinmann, *supra*, at Ex. 45).) He stressed that serum sickness is diagnosed by clinical judgment. Though he acknowledged one might expect an elevated sedimentation rate or low complement levels during the acute phase, he contended there is no biomarker for serum sickness. (Tr. 105-06.) In petitioner's case, he cites headache, dermatologic manifestations, constitutional symptoms, and fatigue, as evidence of a serum sickness reaction. (Tr. 110-11.)

Respondent's experts disagree. Although the symptoms Dr. Tornatore identified are potentially consistent with serum sickness, Dr. He stressed that a serum sickness is a "strong reaction" in which one would also expect manifestations such as fever, edema, and swollen lymph nodes. (Tr. 187.) Additionally, Dr. He explained that inflammatory markers are expected in bloodwork when serum sickness is present. (Tr. 193.) He indicated that if a patient has clinical symptoms, the chances are "pretty slim" that inflammatory markers would be missed by bloodwork. (Tr. 193.) The expected markers for inflammation are fever as well as elevated C-reactive protein and erythrocyte sedimentation rate. (Tr. 192.) Dr. Low testified similarly. (Tr. 220-21, 229.)

28.) Accordingly, he opined that if meningitis was still suspected when petitioner returned with ongoing symptoms the second time, a spinal tap would have been necessary. (Tr. 227.)

[34] The experts also disagree as to whether petitioner's MRI would have been likely to reveal meningitis if it were present. (Tr. 158, 225-26.)

Here, petitioner experienced headaches and neck pain within five days of vaccinations, (Ex. 2, p. 54), arthralgias within a week, (*Id.* at 271), and an evanescent rash within one month. (*Id.* at 261-62, 264). However, there was no fever present and petitioner's initial August 30, 2012 blood work showed no abnormalities. (Ex. 2, p. 126.) More extensive testing from samples collected two weeks later on September 10 and September 14, 2012, further specifically confirmed that C-reactive protein was normal. (Ex. 2, pp. 112, 124.) At the time, Dr. Kashino felt petitioner's symptoms were "very vague" and felt a vaccine reaction was less likely than a viral illness. (Ex. 2, p. 268-70.) Petitioner also demonstrated sinus congestion and prescribed antibiotics helped alleviate at least some of his symptoms. (Ex. 6, p. 2; *see also* n. 7, *supra*.) None of petitioner's physicians at that time suspected a serum sickness-like reaction. It was not until petitioner saw Drs. Kim and Braskett about five months later that they suggested a previously-resolved serum sickness based on the prior history. (Ex. 9, pp. 6-9.) On the whole, it does not appear that petitioner experienced a serum sickness-like reaction.

In any event, even if petitioner did experience a transient serum sickness-like reaction, there is not preponderant evidence that it explains his broader presentation. There is no debate in this case that serum sickness itself is a transient condition. (Tr. 91-92, 188.) And, indeed, when Drs. Kim and Braskett first suspected a serum sickness, they specifically characterized it as previously resolved. (Ex. 9, p. 7.) Thereafter, none of petitioner's treating physicians suggested any *ongoing* serum sickness.

For his part, Dr. Tornatore did not offer any opinion that petitioner's alleged serum sickness caused Sweet's syndrome. (Tr. 107-09.) In fact, he described the two conditions as stemming from two different immune processes (hypersensitivity and complement activation versus autoimmune inflammation) and suggested that he could not discern which started first. (Tr. 86-91, 136-37.) Rather, he opined that although petitioner likely only suffered serum sickness for three to four months, residual symptoms can linger any time an inflammatory event sensitizes a nerve. (Tr. 107-09.) Importantly, however, respondent's experts have strongly stressed the lack of evidence of any systemic inflammatory condition in this case. In fact, the "smoking gun" evidence cited by Dr. Tornatore to demonstrate vaccine causation are aseptic meningitis and the neutrophilic infiltrate on the skin biopsy. (Tr. 161-63.) For the reasons discussed above, these findings are not strong evidence; however, even if they were, they specifically implicate Sweet's syndrome rather than serum sickness. In fact, Dr. Tornatore explicitly testified that the skin biopsy results are not consistent with serum sickness. (Tr. 109.)

Dr. Jaradeh opined that "I felt at the time that the patient's neurologic presentation was that of autonomic neuropathy." (Ex. 30, p. 2.) He suggested it could be secondary to a transient polyradiculitis caused by serum sickness. (Ex. 19, p. 46.) Dr. Low explains, however, that Dr. Jaradeh's assessment of autonomic neuropathy lacks evidence and is based solely on an incorrect interpretation of sympathetic function. (Ex. A, p. 4; *see also* Phillip Low et al., *Effect of Age and Gender on*

Sudomotor and Cardiovagal function and blood pressure response to tilt in normal subjects, MUSCLE & NERVE 1561 (1997) (Ex. A, Tab 4) (explaining adrenergic function tests for autonomic function).) Moreover, if this resulted from polyradiculitis, that condition should have been detected by the EMG/NCS conducted by Dr. Goyal; however, it was not. (Ex. A, p. 4; Ex. 2, p. 165.) And, in any event, Dr. Jaradeh did not explain how serum sickness could lead to autonomic neuropathy. Serum sickness is understood to be a hypersensitivity reaction whereas autonomic neuropathy is generally believed to be an autoimmune condition. (*Compare, e.g.,* Mark H Wener, *Serum sickness and serum sickness-like reactions,* UPTODATE (2018) (Ex. F, Tab 1), *and* Steven Vernino et al., *Autoantibodies to ganglionic acetylcholine receptors in autoimmune autonomic neuropathies,* 343(12) NEW ENG. J. MED. 847 (2000) (Ex. A, Tab 9).) The two conditions implicate different immune responses. (*Accord* Tr. 82-83, 88-89 (Dr. Tornatore explaining hypersensitivity and autoinflammation).)

Thus, if petitioner established only that he experienced a serum sickness, he would not be entitled to compensation even if that serum sickness was vaccine-caused. § 300aa-11(c)(1)(D) (requiring in relevant part that a petitioner "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine"); *see also Wright v. Sec'y of Health & Human Servs.,* 22 F.4th 999, 1005 (Fed. Cir. 2022) (applying traditional tort principles of causation in the context of the Vaccine Act's severity requirement).

iii. Sweet's Syndrome and Serum Sickness Combined

It is also not the case that Dr. Tornatore's reliance on the concurrent or overlapping presence of both serum sickness and Sweet's syndrome provides any added support for his causal opinion. In fact, Dr. Tornatore's decision to invoke both conditions confuses and detracts from the strength of his assessment.

For example, Dr. Tornatore relied on rash as a relevant symptom of both serum sickness and Sweet's syndrome. However, when pressed on details, he offered confusing, if not conflicting, testimony. At the beginning of his testimony, he explained that he felt petitioner's skin biopsy result was diagnostic of Sweet's syndrome and specifically opined that it was not consistent with serum sickness. (Tr. 83-84, 101-02, 109.) I later questioned him regarding the ten rash photographs submitted into evidence and he disclaimed the need to assess individual rashes "because we do have one which clearly showed those phenotype, the pathological features that goes along with an innate dermatologic autoinflammatory response." (Tr. 152.) Especially because the biopsy at issue was taken two years into petitioner's clinical course, this strongly implied the view that petitioner's biopsy result should be viewed as overarching evidence of most, if not all, of petitioner's rashes rather than being an equivocal, or non-specific, outlier as respondent's experts opined.

When turning his attention to serum sickness, however, Dr. Tornatore suggested that at least some of petitioner's rashes should be interpreted as urticaria based on Dr. Jaradeh's records. (Tr. 104-05.) Moreover, when pressed he also acknowledged that

petitioner's photographed rashes are not consistent with what is typically seen in Sweet's syndrome (Tr. 120-21) and also stated regarding the photographs that "I don't have any problem with [respondent's experts] calling it hives because that is something you see with serum sickness-like reactions." (Tr. 114-15). Nonetheless he simultaneously reiterated the significance of the biopsy result, stating "clearly when this was biopsied, there was neutrophils in it. Right? And so you can call it what you want, but it's still inflammatory, and we still end up in the same place." (Tr. 115.) However, this is clearly in contrast to his prior testimony. When I had specifically asked Dr. Tornatore to distinguish the symptoms of Sweet's syndrome from the symptoms of serum sickness, he answered: "I think the skin biopsy shows neutrophil in the skin, that we – is not consistent with serum sickness. Right? Because that's an antibody-antigen complex with complement fixation. So I would say that the skin biopsy, at least for some of the skin manifestations, would not be consistent with serum sickness." (Tr. 109.)

Ultimately, during cross examination Dr. Tornatore acknowledged that he does not know whether petitioner's initial rashes would have been symptoms of the proposed serum sickness or the proposed Sweet's syndrome. (Tr. 145-46.) Moreover, as described above, Dr. Tornatore's opinion regarding petitioner's headache presentation – possibly aseptic meningitis secondary to Sweet's but also possibly headache secondary to serum sickness - presents a similar equivocation. Dr. Tornatore acknowledged that he cannot distinguish what he suggests is Sweet's syndrome from what he suggests is serum sickness and instead opined that he can fall back on the idea that petitioner suffered an undifferentiated, but inherently suspicious, cascade of events. (Tr. 136-37.)

Overall, there is a significant extent to which Dr. Tornatore uses the possibility of both conditions – neuro-Sweet syndrome and serum sickness – to act as a catchall and disguise the fact that neither condition fits well into petitioner's overall clinical presentation. This renders Dr. Tornatore's opinion vague and sometimes inconsistent, reducing his persuasiveness. When I questioned Dr. Tornatore about the timing of the two conditions, he indicated that "I can't give you a clear when did one start and when did the other begin, because I think it really is a spectrum of overlapping symptoms." (Tr. 108.) So, I further asked Dr. Tornatore about specific symptoms. When I asked whether any of petitioner's symptoms fit serum sickness but not Sweet's syndrome, he revealingly indicated: "No. I think there is – serum sickness, the symptoms that I read off are so diffuse, including rheumatologic issues, neurologic issues, skin issues, that that's too hard. I think you could have so many different things that we can't say one of them is not associated with serum sickness. That's – that would be too difficult." (Tr. 109.)

b. *Althen* Test

Because there is not preponderant evidence that petitioner's overall condition can be explained by either Sweet's syndrome, serum sickness, or any combination of the two, there is no need to complete any *Althen* analysis relative to either of those conditions. However, as noted above, even setting aside the specific diagnoses of Sweet's syndrome and serum sickness, Dr. Tornatore contends that there is sufficient evidence of an inflammatory reaction of some kind to substantiate the presence of a

vaccine injury. An *Althen* analysis, especially analysis of *Althen* prong two, demonstrates why Dr. Tornatore's alternative suggestion is inadequate to support petitioner's claim.

i. *Althen* Prong One

Under *Althen* prong one, a petitioner must provide a "sound and reliable" medical theory demonstrating that the vaccine received can cause the type of injury alleged. *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019). Petitioner's theory need only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 549. However, the Federal Circuit has clarified that "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). Instead, petitioner "must provide a reputable medical or scientific explanation that pertains specifically to [their] case." *Moberly*, 592 F.3d at 1322.

Petitioner stresses that "while they are frequently conflated, theory of causation and biologic mechanisms are *not* interchangeable. Petitioner is not required to demonstrate by a preponderance of the evidence the exact mechanism by which vaccines directly affect the human body." (ECF No. 104, p. 2 (emphasis in original).) While it is true that petitioner need not prove a mechanism of causation, petitioner must nonetheless present preponderant evidence that the specific vaccine is capable of causing the specific injury. *See Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359 at *4 (Fed. Cl. Spec. Mstr. July 16, 2004) ("First, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. *In fine*, can [the] vaccine(s) at issue cause the type of injury alleged?"), *aff'd* 64 Fed. Cl. 19 (2005), *aff'd* 451 F.3d 1352 (Fed. Cir. 2006). "The assessment of whether a proffered theory of causation is 'reputable' can involve assessment of the relevant scientific data. Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380.

In his initial expert report, Dr. Tornatore focused first and foremost on the specific conditions of Sweet syndrome and serum sickness. Specifically, he indicated that "I believe Mr. Orgel-Olsen suffered from post-vaccinal Sweet's syndrome and serum sickness, both of which would account for all of his symptoms." (Ex. 32, p. 5.) Dr. Tornatore's discussion of Sweet's syndrome and serum sickness arguably incorporates a broader reliance on autoinflammatory disease and hypersensitivity reactions generally; however, his literature review and reliance materials were limited to evidence purporting to link vaccination and the specific conditions of Sweet's syndrome and serum sickness.[35] (*Id*. at 6.) Because petitioner has not preponderantly established

[35] Dr. Tornatore did file an article by Ponvert and Scheinman that discussed vaccine allergy and pseudo allergy. (Ponvert and Scheinman, *supra,* at Ex. 45.) That article discussed reactions to toxoided vaccines. However, when I asked Dr. Tornatore about the paper during the hearing, he indicated it is

that these diagnoses explain his overall condition, these materials and this discussion are not persuasive in presenting a theory that would otherwise explain how petitioner's unknown condition can be caused by his vaccination(s). Apart from these two specific conditions, Dr. Tornatore's discussion offers no greater explanation than to suggest broadly that the immune system can respond aberrantly to some stimuli. His hearing testimony was similar. (Tr. 83-91.)[36] This is inadequate to support petitioner's claim under *Althen* prong one.

ii. *Althen* Prong Two

Althen prong two requires petitioner to establish by preponderant evidence a "logical sequence of cause and effect" connecting the vaccination and injury at issue. *See Althen*, 418 F.3d at 1278. *Althen* prong two requires a more specific showing that the particular vaccinations petitioner received more likely than not *did* cause the injuries that he alleges. *See, e.g., Doe v. Sec'y of Health & Human Servs.,* 83 Fed. Cl. 157, 166 (Fed. Cl. 2008); *King v. Sec'y of Health & Human Servs.,* 03-584V, 2010 WL 892296, at *87 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (citing *Kuperus v. Sec'y of Health & Human Servs.*, No. 01–60V, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. Sec'y of Health & Human Servs.*, No. 96–518V, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002) ("[I]n many Program opinions issued prior to Althen involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the type of vaccine in question can cause the type of injury in question, and also (2) that the particular vaccination received by the specific vaccinee actually did cause the vaccinee's own injury.")).

Althen prong two is often proven on the strength of treating physician opinion. However, medical records and/or statements of a treating physician 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. *See* 42 U.S.C. §300aa-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

useful only broadly for illustrating the proposition that vaccines trigger innate immune responses. He disclaimed any reliance on any specific findings from the paper. (Tr. 163-65.)

[36] For example, while discussing Sweet's syndrome and the supporting literature, Dr. Tornatore indicated that petitioner "had objective evidence of aberrant, innate immunity on his biopsy, period." (Tr. 83.) He explained that "[w]e like to kind of pigeonhole disease states, but the reality is the immune system [is] a spectrum and . . . people don't necessarily fit very neatly into one category." (Tr. 84.) He further testified that "we have an innate immunity that is affecting the skin, which can be triggered by vaccines . . is kind of at the heart of this case because it's the objective evidence that we have that there was an inflammatory disorder at play here" and "[i]f somebody is predisposed to having their immune system on and that it may irritate the skin, if you were exposed to a foreign antigen via vaccination, for instance, then the immune system may get turned on." (Tr. 84.) Dr. Tornatore also referenced adaptive immunity and molecular mimicry, but only in the context of Sweet's syndrome in particular. (Tr. 86-88.) With regard to serum sickness, Dr. Tornatore discussed hypersensitivity and complement binding and activation. (Tr. 88-91.)

rebutted"). In many cases treating physicians will consider a host of different conditions and causal factors while investigation continues; however, the mere consideration of a possible temporal relationship to vaccination is not the same as reaching a conclusion as to vaccination. Nor does it necessarily mean the physician thinks a suspected causal relationship is likely. *E.g. Stapleford v. Sec'y of Health and Human Servs.,* No. 03-234V, 2009 WL 1456441, at *17 n.24 (Fed. Cl. Spec. Mstr. May 1, 2009) (referencing a temporal relationship to vaccination "is quite different from an indication that such physician has reached a *conclusion* concerning a causal relationship") (emphasis in original), *aff'd*, 89 Fed. Cl. 456 (Fed. Cl. 2009).

Especially important in this case, special masters must consider the medical records as a whole. § 300aa-13(b)(1) ("In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.") The views of treating physicians should weighed against other, contrary evidence also present in the record, including the opinions of other treating physicians. *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 Fed.Appx. 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.Appx. 765 (Fed. Cir. 2012).

In this case, petitioner and Dr. Tornatore are correct that there is a suspicion of vaccine causation throughout petitioner's medical records expressed by multiple treating physicians. There are several reasons, however, why the medical records considered as a whole do not preponderately satisfy *Althen* prong two based on petitioner's treating physicians' views. Although the medical records are described in much greater detail in the fact summary above, given the number of physicians involved, a brief summary of each treating physician's view arranged by discipline helps illustrate:

- **Primary care**: Dr. Kashino, initially felt petitioner's symptoms were "vague" and possibly related to a sinus infection or a viral illness. (Ex. 2, pp. 268, 270.) Although his office completed a VAERS form on petitioner's behalf, Dr. Kashino specified in his own notes that a vaccine reaction was less likely. (*Id*. at 270.) However, as petitioner continued seeing many different specialists, Dr. Kashino later erroneously recorded that these specialists had reached a consensus that a vaccine reaction occurred. (Ex. 2, p. 196; *see also* n. 13-15, *supra*.) Nonetheless, he never reached any final unifying diagnosis of his own.

- **Infectious Disease**: Neither Dr. Kaufman nor Dr. Parsonnet identified any diagnosis within their discipline. Dr. Parsonnet initially suspected fibromyalgia and recommended a rheumatology referral, but later pursued a consultation with

the CDC. She reported the CDC felt vaccine-causation was unlikely without providing further diagnostic assessment. (Ex. 2, p. 245; Ex. 12, p. 66; Ex. 14, p. 12.) Dr. Kaufmann felt there was no unifying infectious disease diagnosis and recorded a vaccine reaction "per patient perception." (Ex. 2, p. 262.)

- **Allergy/Immunology**: Drs. Kim/Braskett suspected a vaccine reaction, especially in the form of a previously resolved serum sickness reaction, but noted petitioner's condition had no clear etiology. They recommended further rheumatology consultation. (Ex. 9, pp. 6-9.) Dr. Felsenstein later indicated that the etiology of petitioner's condition was unclear but recommended further neurology consultation over concern regarding the fasciculations. (Ex. 14, p. 19.)

- **Neurology/Neuromuscular**: Dr. Bhattacharya initially suspected a previously resolved or resolving aseptic meningitis versus a vaccine reaction but felt the likelihood of a neurologic condition was low and recommended a rheumatology consult due to suspicion of inflammatory polyarthropathy. (Ex. 7, pp. 10, 18.) He later indicated right trigeminal autonomic cephalgia but did not otherwise reach a final diagnosis. (*Id.* at 6.) Later, Dr. de la Motte indicated that petitioner was unlikely to have any neurologic condition and felt the symptoms were somatic with no associated pathology. (Ex. 2, p. 167.) Drs. Shieh/Maldonado noted the possibility of a post-vaccine reaction but diagnosed benign fasciculations of unknown etiology. (Ex. 9, p. 9-11.) Dr. Goyal further confirmed on objective testing that the fasciculations had no neurologic pathology, provided no diagnosis, and recommended evaluation by an autonomic specialist. (Ex. 2, pp. 158-63.)

- **Autonomic**: Dr. Jaradeh felt that petitioner had autonomic neuropathy (refuted by Dr. Low). (Ex. 30, p. 3.) Based on the circumstances around the time of onset, he opined that petitioner's condition may have been caused either by his vaccinations in combination with his subsequent treatments or by his sinus infection and/or antibiotics. (*Id*.) He suggested serum sickness "somehow provide[d] some type of inflammation" that affected other body systems, including the autonomic nervous system. (*Id*.)

- **Cardiology**: Dr. Johnson felt there was no unifying diagnosis available for petitioner's symptoms, felt petitioner was fixated on his somatic complaints, and recommended a psychiatric consult. (Ex. 23, pp. 53-54.)

- **Dermatology**: Dr. Shields did not know the cause of petitioner's skin eruptions but questioned whether a rheumatologic disorder could be present. (Ex. 25, p. 7.) Dr. Pincus's interpretation of the skin biopsy was equivocal as discussed above. (*See* n. 28, *supra*.) Drs. Bhutani/Berger subsequently included neutrophilic dermatosis NOS within a differential diagnosis, but cautioned the presentation was not yet characteristic of any condition and recommended keeping an open mind regarding etiopathogenesis. (Ex. 23, pp. 1-2.)

- **Rheumatology**: Dr. Miller opined there was no reactive arthropathy and indicated petitioner's condition was not diagnosable as a rheumatologic condition or infectious disease. He felt a vaccine reaction was "conceivable," but was unprovable speculation. (Ex. 13, pp. 7-10.)

Despite the fact that suspicion of vaccine-causation is repeatedly expressed throughout the medical records, these summaries reveal several important factors that militate against placing any significant weight on such notations. First, when reviewing each physician's individual records, it is clear that, apart from the serum sickness addressed separately above, no single physician was willing to move beyond suspicion of vaccine causation as any explanation for petitioner's overall, prolonged course of symptoms. Second, there is no consensus diagnosis, leaving no clear etiologic explanation for the suspicion of vaccine causation and suggesting that the suspicion was based largely on temporality. Third, and relatedly, most of the suspicion was expressed after the physician in question had exhausted explanations within their own discipline. The suspicion was included along with recommendations for other specialist consultations, suggesting possibilities beyond the opining physician's own discipline. However, these suspicions were not borne out by the relevant specialist's evaluation.[37] And, fourth, many of petitioner's treating physicians also explicitly expressed doubt as to the existence any connection to petitioner's vaccination. Selectively accepting the opinions of some of petitioner's treating physicians necessarily means rejecting the opinions of others; however, given the lack of a unifying diagnosis, the equivocation of those physicians suspecting vaccine-causation, and the lack of unanimity among petitioner's treating physicians as to the possible cause(s) of petitioner's symptoms, there is little basis on this record to justify such a preference when considering the record as a whole. Petitioner himself testified that his physicians were, in effect, stumped by his presentation. (Tr. 31-32.)

Dr. Tornatore nonetheless testified: "the bottom line is everyone keeps saying this is a post-vaccination inflammatory event. Whether they use the term 'sweet's syndrome or 'serum sickness' is irrelevant. They're all saying the same thing." (Tr. 144.) Describing petitioner's "weird symptoms," he contended that "you just draw a straight line across and it makes sense." (Tr. 178.) In light of the above, and especially in light of Dr. Tornatore's own failure to persuasively crystalize petitioner's clinical history, this is not persuasive. Dr. Tornatore's rationale implies that the repeated suspicion of multiple physicians has a cumulative effect that increases the likelihood that a vaccine reaction occurred in some form. But this is not true in this case. These physicians are all simply recording the same initial suspicion of temporality observed by

[37] For example, Drs. Parsonnet (infectious disease), Kim/Braskett (allergy/immunology), and Shields (dermatology), all suggested the answer may be found by rheumatology, but petitioner's rheumatologist felt no unifying rheumatology diagnosis is available and that vaccine causation was unprovable speculation. Similarly, Drs. Kim/Braskett and Dr. Felsenstein (allergy/immunology) recommended a neurology follow up due to concerns regarding petitioner's fasciculations, but Drs. Shieh/Maldonado and Dr. Goyal later determined they were benign and had no neurologic cause.

petitioner.[38] It is not consensus, only repetition brought about by the sheer number of consultations petitioner sought and the inability of any physician to confidently pin-point the correct diagnosis. There is little to no evidence that the suspicion, no matter how many times repeated, ever progressed to anything approaching a substantiated conclusion. Indeed, Dr. Tornatore's suggestion that an inflammatory injury is supported by the medical records is predicated in large part by his assumptions that petitioner's headache presentation constituted aseptic meningitis and that his skin biopsy proves his recurrent rashes to be a manifestation of an inflammatory condition. However, for the reasons discussed above, he is not persuasive on either point. This holds true regardless of whether these factors contribute to a specific diagnosis. Additionally, respondent's experts are persuasive in stressing that petitioner's blood work throughout this period remained remarkably free of any indicators of systemic inflammation.

iii. *Althen* Prong Three

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). Here, it is clear that petitioner experienced headaches and neck pain within five days of vaccinations, (Ex. 2, p. 54), arthralgias within a week, (*Id.* at 271), and an evanescent rash within one month. (*Id.* at 261-62, 264). Prior program experience suggests that it is plausible that an immunologic reaction could occur in that timeframe. In this case, it certainly formed the basis for petitioner's own subjective belief that his vaccines caused his condition and likely accounts for the suspicion of vaccine causation entertained by his treating physicians. However, petitioner's failure to establish *Althen* prongs one and two necessarily means petitioner cannot prevail on *Althen* prong three. The explanation for what is a medically acceptable timeframe must coincide with the theory of how the relevant vaccine can

[38] "A treating physician's recognition of a temporal relationship does not advance the analysis of causation." *Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *26 (Fed. Cl. Spec. Mstr. July 30, 2012); *see also Devonshire v. Sec'y of Health & Human Servs.,* No. 99-031V, 2006 WL 2970418, at *19 (Fed. Cl. Spec. Mstr. Sept. 28, 2006) (medical expert's "*post hoc ergo prompter hoc* reasoning…has been consistently rejected by the Court and is 'regarded as neither good logic nor good law'") (quoting *Fricano v. U.S.,* 22 Cl. Ct. 796, 800 (1991) (emphasis in original)). Additionally, it is clear from the contemporaneous records that this recognition of the possible temporal relationship often made its way into the medical records merely due to petitioner's insistence. Such instances are less persuasive vis-à-vis the treating physician's own views of causation. *E.g., Moriarty by Moriarty v. Sec'y of Health & Human Servs.,* No. 03-2876V, 2014 WL 4387582, at *15 (Fed. Cl. Spec. Mstr. Aug. 15, 2014) (petitioner's parent's "views about causation are not persuasive because she is not a medical doctor'"), *review denied, decision aff'd,* 120 Fed. Cl. 102 (2015), *vacated and remanded on other grounds,* 844 F.3d 1322 (Fed. Cir. 2016); *accord* 42 U.S.C. § 300aa–13 (a special master may not find in favor of the petitioner "based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion"); *James-Cornelius v. Sec'y of Health & Human Servs.,* 984 F.3d 1374, 1380 (Fed. Cir. 2021) ("lay opinions as to causation or medical diagnosis may be properly characterized as mere 'subjective belief' when the witness is not competent to testify on those subjects[.]")

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.*, 503 Fed.Appx. 952 (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). Here, however, there is no clear diagnosis and no clear theory of causation.

VI. Conclusion

During the hearing, petitioner's counsel expressed concern that the government views petitioner as a malingerer. In that regard, I stress that this decision reaches no such conclusion. I sympathize with petitioner both for what he has experienced medically and for the distress he has experienced in finding himself unable to uncover a satisfactory explanation for his condition. Perhaps unsurprisingly, however, this legal Program cannot achieve for petitioner the clarity that eluded his many treating physicians. It is petitioner's burden to establish a vaccine-caused injury has occurred; however, for all the reasons stated above, I find that petitioner has not established his case by preponderant evidence and is therefore not entitled to compensation. Therefore, this case is dismissed.[39]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[39] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.