In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 18, 2020

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MARLIE BARLOW,	*	PUBLISHED
	*	
Petitioner,	*	No. 17-513V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on the Record; Influenza ("Flu") Vaccine; Peripheral Neuropathy; Carpal Tunnel Syndrome ("CTS"); Significant Aggravation.
	*	
Respondent.	*	
	*	
* * * * * * * * * * * * * * * * * * *		

Joseph A. Vuckovich, Maglio Christopher and Toale, P.A., Washington, DC, for petitioner.
Camille M. Collett, United States Department of Justice, Washington, DC, for respondent.

DECISION[1]

I. INTRODUCTION

On April 12, 2017, Marlie Barlow ("petitioner") filed a petition under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"),[2] 42 U.S.C. § 300aa-10 et seq. (2012), alleging left shoulder and left arm pain following an influenza ("flu") vaccination administered on October 2, 2015. Petition at ¶¶ 1, 3, 6, 9. Subsequently, petitioner alleged that the vaccination significantly aggravated his left arm peripheral neuropathy and carpal tunnel syndrome ("CTS"). Petitioner's Motion for Findings of Fact and Conclusions of

[1] Because this Decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this Decision on the website of the United States Court of Federal Claims, in accordance with the E- Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b).

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

Law ("Pet. Mot."), filed Nov. 15, 2019, at 1 (ECF No. 31).

Petitioner has suffered serious and significant illnesses. However, after carefully analyzing and weighing all of the evidence and expert reports presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner is not entitled to compensation. Therefore, petitioner's case must be dismissed.

II. PROCEDURAL HISTORY

Petitioner, Mr. Marlie Barlow, filed for compensation under the Vaccine Act on April 12, 2017. Petition at 1. Initially, petitioner alleged that he suffered left shoulder and arm pain following the flu vaccine that he received on October 2, 2015. Petition at ¶¶ 3, 6, 9. However, subsequently, petitioner alleged that the receipt of a flu vaccine significantly aggravated existing peripheral neuropathy in his left arm and significantly aggravated his left arm CTS.[3] Pet. Mot. at 1. Petitioner filed medical records on June 27, 2017. Petitioner's Exhibits ("Pet. Exs.") 1-4. Respondent filed a status report on October 6, 2017, indicating that petitioner had missing medical records. Respondent's Status Report ("Resp. Status Rept."), filed Oct. 6, 2017 (ECF No. 10). On October 10, 2017, petitioner filed additional medical records. Pet. Ex. 5.

On January 22, 2018, respondent filed a Motion to Stay the Rule 4(c) Report. Resp. Mot. to Stay, filed Jan. 22, 2018 (ECF No. 15). In a non-PDF Order, the Court denied respondent's motion. Non-PDF Order Denying Motion to Stay dated Jan. 23, 2018. Respondent filed the Rule 4(c) Report on February 7, 2018 recommending against compensation. Resp. Rept. at 1 (ECF No. 17).

On August 17, 2018, petitioner filed a Motion to Stay Proceedings on the ground that the parties had agreed to explore settlement. Pet. Mot. to Stay Proceedings, filed Aug. 17, 2018, at 1 (ECF No. 20). Petitioner indicated that he had transmitted a demand to respondent on August 15, 2018. Id. Settlement discussions were not productive, and, following a status conference held on September 20, 2018, the Court issued a non-PDF Order setting a new deadline for petitioner's expert report. Non-PDF Scheduling Order dated Sept. 20, 2018.

On November 9, 2018, petitioner filed an expert report from Dr. Brad Klein accompanied by supporting medical literature. Pet. Exs. 6-12. On May 30, 2019, respondent filed an expert report from Dr. Miles Steven Evans. Resp. Ex. A. On July 11, 2019, petitioner filed additional medical records. Pet. Ex. 13. Petitioner then filed a supplemental expert report and additional medical literature from Dr. Klein on July 31, 2019. Pet. Exs. 14-18.

The Court held a status conference on September 5, 2019, and the special master issued a non-PDF Scheduling Order setting a briefing schedule for this matter. See Non-PDF Scheduling Order dated Sept. 5, 2019. On October 3, 2019, this case was reassigned to the undersigned. Notice of Reassignment dated Oct. 3, 2019 (ECF No. 29). Respondent filed a supplemental expert report from Dr. Evans on November 1, 2019. Resp. Ex. C.

On November 15, 2019, petitioner filed a Motion for Findings of Fact and Conclusions of

[3] The undersigned has analyzed causation and significant aggravation as both have been alleged.

Law. Pet. Mot. On February 12, 2020, respondent filed a response to petitioner's motion. Resp. Response to Pet. Brief in Support of His Claim ("Resp. Response"), filed Feb. 12, 2020 (ECF No. 37). On March 9, 2020, petitioner filed a second supplemental report from Dr. Klein and a Reply to respondent's brief. Pet. Ex. 20; Reply Memorandum in Support of Pet. Mot. ("Pet. Reply"), filed Mar. 9, 2020 (ECF No. 39).

Pursuant Vaccine Rule 3(b)(2), special masters must "afford[] each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review of the special master's decision." Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1366 (Fed. Cir. 2020). Vaccine Rule 8(d), also provides that "the special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." Id. at 1365. Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to afford each party a "full and fair opportunity to present its case." Hovey v. Sec'y of Health & Hum. Servs., 38 Fed. Cl. 397, 400-01 (Fed. Cl. 1997) (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." Id. at 401; see also Kreizenbeck, 945 F.3d at 1366. Here, the petitioner has filed complete medical records and the parties have filed a number of expert reports and supportive medical literature. Additionally, they have fully briefed the issues. Therefore, the undersigned finds that the record is sufficiently developed to allow a thorough analysis and decision regarding entitlement.

III. ISSUES TO BE DECIDED

The parties dispute causation. Petitioner asserts that his flu vaccination caused and/or significantly aggravated his existing peripheral neuropathy and CTS, and maintains that he has proven by preponderant evidence the standards articulated in Althen and Loving. See Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005); Loving v. Sec'y of Health & Hum. Servs., 86 Fed. Cl. 135, 142-44 (2009). Respondent disagrees. Respondent contends that petitioner's claim fails because he has not satisfied the Althen requirements. Resp. Response at 1-2.

IV. FACTUAL SUMMARY

A. Petitioner's Past Medical History

Petitioner was eighty-two years old at the time of vaccination, and had an extensive and complicated medical history, including significant cardiac problems. Petitioner is left-hand dominant. Pet. Ex. 5 at 258.

On May 9, 2011, petitioner was treated for dysuria, constipation, and an abdominal mass. Pet. Ex. 3 at 784. His problem list for this visit included coronary artery disease, cardiomyopathy, type II diabetes, history of right frozen shoulder, and history of pulmonary emboli. Id. at 784-85. He was diagnosed with acute kidney injury secondary to obstructive uropathy, prostatic hypertrophy/hyperplasia, worsening bilateral lower extremity edema, chronic left lower extremity deep venous thrombosis, and congestive heart failure. Id. at 786. In November 2011, his records indicate that he required the use of a walker. Pet. Ex. 2 at 186.

On December 19, 2012, petitioner was seen by Dr. Merritt Hougen, his primary care doctor, for a review of EKG and echocardiogram results. Pet. Ex. 2 at 161-66. The notes from this visit discuss the patient's diabetes and his "mild peripheral neuropathy" and "mild peripheral numbness," as well as his diminished peripheral sensation. Id. at 161, 163. Petitioner's assessment for this appointment included diabetes mellitus, type II diabetes mellitus with peripheral circulatory disorder, (lower) leg localized swelling bilateral, chronic non-decubitus ulcer of the toes of the right foot, chronic peripheral venous insufficiency, coronary artery disease, hypertension, and hyperlipidemia. Id. at 161. Dr. Hougen noted that petitioner's peripheral edema had "markedly improved." Id. Physical examination revealed 1-2+ peripheral edema.[4] Id. at 162.

Throughout 2013, petitioner's medical records show that he had chronic peripheral edema, often categorized as 2 or 3+. For example, on June 4, 2013, petitioner's records show 2+ peripheral edema. Pet. Ex. 2 at 137. On September 30, 2013, petitioner presented to Dr. Hougen for cellulitis, exacerbation of peripheral neuropathy, and venous stasis due to insect bites. Id. at 129. He had "2+ peripheral edema with increased local left ankle edema." Id. at 129, 131. His blood glucose level was elevated at 145 mg/dL.[5] Id. at 132. On October 14, 2013, petitioner had 2+ peripheral edema with increased left ankle edema, and on October 31, he had 3+ pitting edema at the ankles. Id. at 120, 127.

On January 6, 2014, petitioner was seen by Dr. Virginia Knight at Scripps Urgent Care after injuring his left wrist while lifting heavy boxes. Pet. Ex. 2 at 290. His wrist was "swollen and painful" with "some throbbing into his left fingers." Id. Physical examination revealed moderate bruising and edema of the wrist with limited range of motion. Id. Additionally, petitioner had "redness and streaking extending up the anterior forearm." Id. at 291. X-rays showed "scaphoid lunate separation and chondrocalcinosis and osteoarthritis" without evidence of "fracture or dislocation." Id. at 292. Petitioner was diagnosed with acute left wrist trauma and cellulitis. Id.

Petitioner had a follow-up visit for his wrist injury on January 15, 2014 with Dr. Lorenzo Pacelli. Dr. Pacelli diagnosed petitioner with "possible rupture of the flexor carpi radialis tendon."[6] Pet. Ex. 2 at 265. After a discussion of treatment options, petitioner elected

[4] Edema is the presence of abnormal fluid in subcutaneous tissues, often due to renal or heart failure. Dorland's Illustrated Medical Dictionary 587 (33d ed. 2020). In pitting edema, pressure applied to the tissues reveals pits. Id. It may be quantified on a scale of 1+ to 4+ with 4+ being most severe. Id.

[5] For fasting glucose samples, the American Diabetes Association recommended decision limits are: 70-99 mg/dL is Normal; 100-125 mg/dL is Impaired Fasting Glucose; >125 mg/dL is Diabetes. Pet. Ex. 2 at 97.

[6] The flexor carpi radialis tendon is a radial flexor muscle extending from the wrist to the base of second metacarpal, or index finger. Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=90710 (last accessed May 28, 2020). The innervation of this muscle is provided by the median nerve and allows for flexion and abduction of the wrist joint. Id.

conservative treatment. Id.

On April 17, 2014, petitioner developed congestive heart failure and had a dual-chamber pacemaker placed for sick sinus syndrome. Pet. Ex. 2 at 103. He then experienced abdominal discomfort and was diagnosed with acute cholecystitis. Id. Following robotic surgery, he was discharged, and subsequently readmitted with ischemic cardiomyopathy. Id. His discharge summary indicated that he had three hospitalizations in one month's time for congestive heart failure. Id.

Moving forward to 2015, petitioner was seen by Dr. Hougen on January 13, 2015, for recent abrasive trauma to his head. Pet. Ex. 2 at 56. Dr. Hougen documented the presence of 2+ peripheral edema and weeping cellulitis of the left leg. Id. at 56-59. On June 23, 2015, Dr. Hougen saw petitioner and noted 2+ peripheral edema with "marked left leg cellulitis." Id. at 45.

B. Petitioner's Vaccination and Post-Vaccination Medical History

On October 2, 2015, petitioner received a Fluzone high-dose flu vaccination in his left shoulder. Pet. Ex. 1 at 1. On October 8, 2015, he was seen at a Scripps Urgent Care facility by Dr. Steven Henderson for a pruritic skin eruption. Pet. Ex. 2 at 285-86. Physical examination showed scabbing and excoriations of the bilateral shoulders, chest, and base of the neck. Id. at 286. Petitioner reported that he had a history of sensitive skin, and thought that the rash was due to a change in detergent. Id. Dr. Henderson's diagnosis was "some type of exposure with secondary staph infection," dermatitis, and possible occult scabies. Id. Petitioner was placed on a steroid and Eurax cream. Id. Dr. Henderson did not document any swelling, edema, bruising, or numbness of petitioner's left shoulder, forearm, or wrist.

Petitioner was seen on October 22, 2015, by his cardiologist physician assistant, Ms. Saunders, P.A. Pet. Ex. 2 at 34. Petitioner reported that over the prior week, he had increasing swelling of his legs. Id. at 35. Petitioner did not report swelling of his arms. Ms. Saunders performed and documented a physical examination, which revealed 2-3+ pitting edema of both legs, left greater than right and "[i]ndurated erythematous warm tissue left leg," indicating cellulitis. Id. at 34, 37. Ms. Saunders did not document any pain, swelling, edema, bruising, or numbness of the left arm, forearm, or wrist.

Petitioner was seen again by Ms. Saunders on October 27, 2015, for continued management of his fluid overload and congestive heart failure. Pet. Ex. 2 at 30; Pet. Ex. 5 at 67-69; Pet. Ex. 13 at 157. At that visit, Ms. Saunders noted that petitioner had an abnormal stress test positive for ischemic cardiomyopathy. Pet. Ex. 5 at 67-69. He was diagnosed with coronary artery disease, cardiomyopathy, and congestive heart failure. Id. at 67. Ms. Saunders documented mild swelling of petitioner's right and left legs. Id. Ms. Saunders did not document swelling, edema, bruising, numbness, or pain of petitioner's shoulders, forearms, or wrists.

On November 24, 2015, petitioner presented to Scripps Dermatology outpatient center and was seen by Dr. Roger Cornell for complaints of a spot on his cheek and a rash on his lower left leg. Pet. Ex. 2 at 28. Petitioner reported that he had the spot on his right cheek for over two years and the rash on his leg for one month. Id. Petitioner also told Dr. Cornell that his arthritis

was better. Id. Under the review of symptoms, Dr. Cornell checked "no" under "other problems elsewhere on the skin," as well as "no" under additional musculoskeletal issues. Id. at 29. Dr. Cornell did not document any swelling, edema, bruising, numbness, or pain related to petitioner's left shoulder, forearm, or wrist.

On December 3, 2015, petitioner had a follow up appointment with Dr. Hougen. Pet. Ex. 2 at 20. Dr. Hougen stated that Mr. Barlow was doing well, and had "excellent reduction of his peripheral edema." Id. at 19. Dr. Hougen specifically noted that petitioner had right shoulder pain. Id. at 20. Dr. Hougen stated, "[h]e has marked compromise of his right shoulder given his walker and degenerative changes of the shoulder." Id. at 19. Petitioner was to see orthopedics for a possible injection for degenerative joint disease in his right shoulder. Id. Dr. Hougen inspected petitioner's "joints, bones, and muscles" and noted that he had a "[f]rozen right shoulder with marked crepitus." Id. at 23. Dr. Hougen also documented that petitioner had occasional foot numbness. Id. at 20. Petitioner's "strength [was] 5/5 in upper and lower extremities." Id. at 23. Petitioner's skin examination revealed that his cellulitis was "markedly diminished." Id. Petitioner's blood glucose level was elevated at 151 mg/dL. Id. at 307. Dr. Hougen did not document any swelling, edema, bruising, numbness, or pain related to petitioner's left shoulder, forearm, or wrist.

Petitioner complained to Dr. Hougen of his right shoulder pain again on February 2, 2016. Pet. Ex. 2 at 10-19. Dr. Hougen order an X-ray and physical therapy. Id. at 10. Dr. Hougen again performed a physical examination, noting that petitioner had marked right glenohumeral crepitus with abduction restricted to 70° in his right shoulder. Id. at 14. Dr. Hougen's skin examination showed resolving cellulitis and stasis dermatitis in his leg. Id. Dr. Hougen did not document pain, swelling, edema, numbness, or bruising of petitioner's left shoulder, forearm, or wrist.

The first documentation of Mr. Barlow's complaints related to his left arm occurred on March 19, 2016, five months after the administration of the flu vaccination. Pet. Ex. 5 at 294. Mr. Barlow presented to Scripps Urgent Care where he was evaluated by Dr. Robert K. Kakehashi. Pet. Ex. 2 at 283-84. Dr. Kakehashi wrote,

> The patient . . . complains of left arm numbness and tingling since receiving a flu shot in October. He states that he received a flu vaccination on the left upper arm. He recalls that there is something wrong with the first injection and he received a second injection immediately in the same area. Following this, he noted swelling and firmness of that area as well as the appearance of ecchymoses of the biceps region which did extend down to his forearm. This slowly resolved . . . but he did note some swelling of his forearm. He states that he has pain of the biceps area that radiates down the radial aspect of his forearm and he claims that he has numbness of his 3rd, 4th, and 5th digits.

Id.

Dr. Kakehashi examined petitioner's left arm and noted two dried scabs of his biceps deltoid region with what appeared to be residual halo of ecchymoses. Pet. Ex. 2 at 284. There

was no fluctuance or firmness in the area and palpation of the upper arm and lower arm revealed no cords or crepitus. Id. Grip strength was 5/5. Id. Dr. Kakehashi assessed Mr. Barlow with "left arm paresthesias since receiving the flu vaccination." Id. Dr. Kakehashi did not note swelling or edema of petitioner's left shoulder, forearm, or wrist.

Mr. Barlow was subsequently seen by neurologist, Dr. John S. Romine, on March 28, 2016. Pet. Ex. 2 at 261-63. Dr. Romine recorded, "patient states that in October of last year, he had a flu shot in the left upper arm and the area 'turned purple' and was painful. He states that the whole arm turned purple, but over time this has gradually resolved." Id. at 262. On examination, Dr. Romine noted, "[t]here is a residual faint halo of chemosis[7] around the left deltoid region laterally in the left upper extremity. There is mild swelling of the left forearm." Id. "Sensory examination reveals inability to distinguish sharp from dull in the thumb, index, and middle fingers. There also decrease to touch in the distribution of the left radial, sensory cutaneous nerve." Id. Initial diagnoses were "[s]tatus post remote flu immunization (October 2015); local reaction with ecchymosis and swelling of the left upper extremity, improved" and "[p]robable left carpal tunnel syndrome; possible left radial, sensory cutaneous neuropathy." Id.

On April 19, 2016, petitioner was seen again by Dr. Romine, complaining of persistent numbness in the thumb, index, and middle fingers. Pet. Ex. 5 at 41. Electromyography ("EMG") of his left arm showed severe left median neuropathy at the wrist and coexistent diffuse mild sensory motor polyneuropathy. Id. at 523. Needle EMG was normal in the first dorsal interosseous, extensor indicis, pronator, deltoid, triceps, and biceps muscles. Id. There were mild chronic neurogenic changes confined to the abductor pollicis brevis muscle.[8] Id. Dr. Romine opined, "electrodiagnostic studies done today confirmed severe left carpal tunnel syndrome. In addition, there is associated mild coexistent sensory motor neuropathy, which is probably idiopathic." Id. at 41. Dr. Romine believed the main source of symptoms was the significant left CTS. Id. He referred petitioner to an orthopedic hand surgery specialist. Id. Dr. Romaine did not attribute petitioner's severe CTS or mild sensory motor neuropathy to his prior flu vaccination.

On April 21, 2016, petitioner was seen in consultation by orthopedist Dr. Jake Hamer. Pet. Ex. 2 at 258; Pet. Ex. 5 at 259. Petitioner gave a history of discomfort in his left arm from his shoulder to his hand associated with numbness and tingling in the thumb, index, and middle fingers. Pet. Ex. 2 at 258. Dr. Hamer noted, "[h]e believes his symptoms began on October 2, 2015, after . . . the flu shot." Id. On examination petitioner had mild left thenar atrophy, negative Tinel's of the ulnar nerve at the elbow, but positive Tinel's over the median nerve at the wrist with 4+/5 strength in the abductor pollicis brevis. Id. at 260. Diagnosis was severe chronic left CTS and endoscopic left carpal tunnel release was recommended. Id. Dr. Hamer did not

[7] Chemosis is inflammation of the conjunctiva, an eye membrane. Pet. Mot. at 18 n.1. Petitioner suggests that taken in context, Dr. Romine probably meant to write "ecchymosis." Id.

[8] The abductor pollicis brevis is a muscle located in the hand between the wrist and the base of the thumb. Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=90615 (last accessed Apr. 20, 2020). This muscle allows for the abduction of the thumb, or to move the thumb away from the palm. Id.

note any association between petitioner's flu vaccination and his CTS.

Petitioner had a pre-operative physical with Dr. Hougen on April 25, 2016. Pet. Ex. 5 at 246. Dr. Hougen noted "both peripheral neuropathy and his median neuropathy reviewed at his request. Peripheral neuropathy is consistent with diabetes. He has a left median nerve diagnostic EMG nerve conduction consistent with carpal tunnel syndrome." Pet. Ex. 2 at 247. Dr. Hougen stated, "[h]e equates this to [flu] shot. However, EMG and nerve conduction shows a median nerve entrapment at the carpal tunnel." Id.

Petitioner underwent endoscopic left carpal tunnel release surgery on May 23, 2016. Pet. Ex. 2 at 255; Pet. Ex. 5 at 254-55. There were no complications. During a follow-up visit on May 31, 2016, Dr. Hamer noted that petitioner's surgical incision was healing well without redness or drainage. Pet. Ex. 2 at 4. Dr. Hamer explained that due to petitioner's "severe carpal tunnel syndrome, he may not appreciate change in sensation even over time." Id.

On June 8, 2016, petitioner saw Dr. John Kelso, an immunologist at Scripps Clinic. Pet. Ex. 5 at 257. During the visit, Dr. Kelso took a history from petitioner, stating that petitioner "reports that on October 2, 2015 he received the Fluzone high-dose influenza vaccination in his left arm. Later that day he had some redness around the injection site. By the next day he developed bruising at the site and lower down onto arm below the elbow." Id. Dr. Kelso also wrote, "[h]e recently underwent [] nerve release in his wrist but this has not helped as yet." Id. During the physical examination, Dr. Kelso noted "some bruising discoloration of his left arm."[9] Id. Dr. Kelso assessed petitioner with "neuromuscular and dermatologic abnormalities following influenza vaccination." Id. Dr. Kelso suggested that petitioner's neurologic symptoms may have been secondary to brachial neuritis due to reports describing brachial neuritis after injections,[10] thought to represent an inflammatory response around nerves and/or be related to the trauma of the injection itself. Id. Dr. Kelso thought the dermatologic abnormalities were not associated with brachial neuritis, but may have represented a delayed hypersensitivity reaction. Id.

> There are no tests to definitively prove that the abnormalities are the result of the immunization although the temporal association makes this seem likely and a report will be filed with the vaccine adverse event reporting system (VAERS). The only conceivable treatment would be corticosteroids to dampen the inflammation although the inflammation has likely come and gone with a resultant nerve damage and skin changes and the corticosteroids would likely not be helpful at this point.

Id. He recommended avoiding further injections in the left arm. Id.

[9] The undersigned notes that the bruising described at this visit was likely due to petitioner's recent CTS surgery.

[10] Dr. Kelso's observation is consistent with the Vaccine Injury Table, which identifies brachial neuritis as a covered injury for vaccines containing tetanus toxoid. See §§ 11(c)(1), 13(a)(1)(A). Brachial neuritis is defined as follows: "dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition." 42 C.F.R. § 100.3(c)(6) (2020).

Petitioner saw Dr. Hougen for congestive heart failure and persistent left arm numbness and pain on July 12, 2016. Pet. Ex. 5 at 29. Petitioner related his medical history to Dr. Hougen, who noted, "felt to be contributed by a polyneuropathy secondary to his injection along with severe carpal tunnel syndrome and a left shoulder adhesive capsulitis." Id. Dr. Hougen performed a physical examination and noted, "[l]eft supraspinatous tenderness with restricted range of motion to 80°." Id. at 33. He also documented "stasis dermatitis with peripheral edema." Id.

On March 21, 2017, petitioner followed up with Dr. Romine, who noted lack of improvement of carpal tunnel symptoms and diagnosed him with persistent numbness and sensory deficit of the left arm and hand. Pet. Ex. 5 at 19-20. Dr. Romine's physical examination showed petitioner had "weakness of the left [abductor pollicis brevis] with otherwise normal motor function in the upper extremities." Id. Petitioner saw Dr. Hamer the same day. Id. at 21-22. Dr. Hamer reported "[p]ersistent numbness and tingling in the left hand despite carpal tunnel release" and commented that the patient would "have numbness and tingling chronically, which will not completely resolve." Id. at 22.

Petitioner saw Dr. Romine again on April 6, 2017. Pet. Ex. 5 at 3. Dr. Romine noted, "he relates the history of the [] symptoms appearing following a flu shot in October 2015, which the arm became numb and swollen and red with eventual resolution of those symptoms with persistence of the sense of numbness." Id. Dr. Romine's diagnoses were, "1) status post left carpal tunnel release-persistent numbness of hand as well as forearm-localization/cause unclear. 2) Persistent numbness and sensory deficit of left forearm and hand status post remote flu shot - ? possible residual post immunization brachial neuritis?" Id. at 3-4.

As of April 7, 2019, both CTS and "upper extremity neuropathy (chronic)" were listed among Mr. Barlow's active problems in his medical record. Pet. Ex. 13 at 11.

C. Petitioner's Affidavit

In his affidavit, petitioner stated that he received a Fluzone high-dose flu vaccination. Pet. Affidavit ("Aff.") at ¶ 1. Petitioner alleges that he sustained a left shoulder injury which was caused by the vaccine and that he suffered the residual effects and complications of the injury for more than six months after the administration of the vaccine. Id. at ¶¶ 3-4.

D. Carpal Tunnel Syndrome

The American Academy of Orthopaedic Surgeons Clinical Guidelines on the Diagnosis of CTS defines CTS as a symptomatic compression neuropathy of the median nerve at the level of the wrist. Pet. Ex. 9 at 2. The median nerve, which runs from the forearm into the palm of the hand, provides sensation to the fingers and controls certain muscles at the base of the thumb. Pet. Ex. 6 at 8. The carpal tunnel, a bony canal consisting of carpal bones, contains flexor tendons and the median nerve which enter the tunnel in the midline of the wrist or slightly radial to it. Pet. Ex. 9 at 3. CTS is a neuropathy caused when the tendons of the carpal tunnel are

irritated and become swollen, resulting in compression of the median nerve at the wrist. Id. at 2. As the median nerve is compressed, it becomes irritated and inflamed. Id.

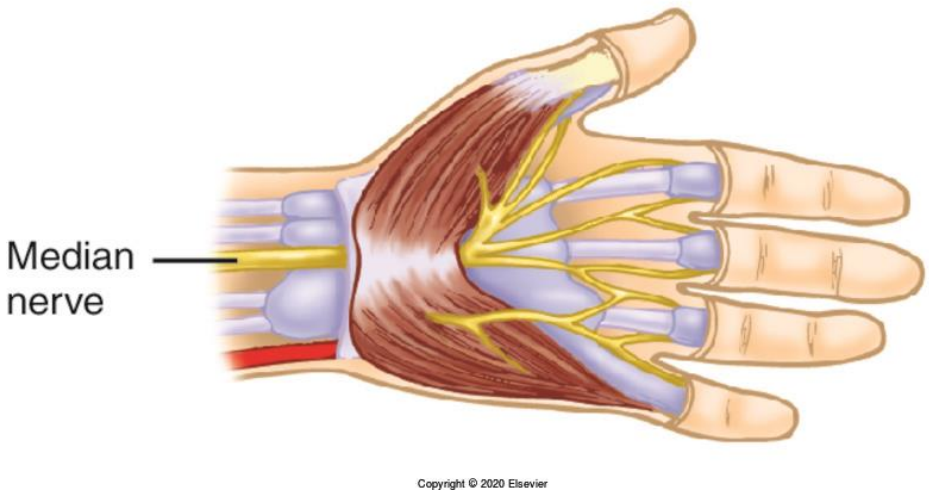

Figure 1.[11]

Ibrahim et al.[12] identifies CTS as the most frequent entrapment neuropathy, believed to be present in 3.8% of the general population. Pet. Ex. 9 at 2. Symptoms of CTS include pain in the hand, unpleasant tingling, pain or numbness in the distal distribution of the median nerve (thumb, index, middle finger and the radial side of the ring finger), and a reduction of the grip strength and function of the affected hand. Id. at 3. The most significant risk factors of CTS include, "prolonged postures in extremes of wrist flexion or extension, repetitive use of the flexor muscles, and exposure to vibration." Id. at 3-4. Other risk factors include conditions that alter the fluid balance in the body and increase the volume in the carpal tunnel, such as pregnancy, obesity, renal failure, hypothyroidism, use of oral contraceptives, and congestive heart failure. Id. at 4. Neuropathic factors, such as diabetes, alcoholism, vitamin toxicity or deficiency, and exposure to toxins, can also play a role in triggering CTS. Id. Diabetic patients tend to develop the condition due to their reduced threshold for sustaining nerve damage. Id. An MRI may be used to determine whether surgery is appropriate. Id. at 5. If performed, an MRI may show swelling of the median nerve or its myelin sheath. Id.

CTS is more common in females than in males, and its occurrence is commonly bilateral with a peak age range of 40 to 60 years, although it occurs in all age groups. Pet. Ex. 9 at 1. The treatment of CTS falls under two categories: conservative and surgical. Id. at 5.

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[11] This image shows the median nerve within the in carpal tunnel. Image taken from Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110370&searchterm=carpal+tunnel+syndrome (last accessed on Apr. 29, 2020).

[12] I. Ibrahim et al., Carpal Tunnel Syndrome: A Review of the Recent Literature, 6 Open Orthopaedics J. 69 (2012).

E. Expert Qualifications and Opinions

i. Expert Qualifications

a. Petitioner's Expert, Dr. Brad Klein

Dr. Brad Klein is a board-certified neurologist by the American Board of Psychiatry and Neurology. Pet. Ex. 6 at 1. He majored in both biology and psychology at Rutgers College, New Jersey, and graduated with highest honors, equivalent to summa cum laude. Id. Dr. Klein received his M.D. from Jefferson Medical College, in Philadelphia, and then completed a year of medical residency, followed by three years of neurology residency, and a year-long fellowship in headache and neuromuscular medicine at Thomas Jefferson University in Philadelphia. Id. He is currently a Clinical Associate Professor of Neurology at Sidney Kimmel Medical College of Thomas Jefferson University and the Medical Director of Abington Headache Center at Abington Memorial Hospital in Abington, Pennsylvania. Pet. Ex. 7 at 1.

b. Respondent's Expert, Dr. Miles Steven Evans

Dr. Miles Steven Evans is a practicing general neurologist subspecializing in the diagnosis and treatment of epilepsy. Resp. Ex. A at 1. He graduated cum laude from the University of Kentucky with a major in psychology. Resp. Ex. B at 1. Dr. Evans received his M.D., cum laude, from the University of Louisville School of Medicine. Id. He completed his neurology residency training and chief residency at Barnes Hospital and the Washington University School of Medicine. Id. After residency, he completed a research fellowship in neuropharmacology, the National Research Service Award, at the same institution. Resp. Ex. A at 1. He is currently a professor in the Department of Neurology of the University of Louisville, in Louisville, Kentucky and was formerly Professor of Neurology and Microbiology/Immunology at the Southern Illinois University School of Medicine, in Springfield, Illinois. Id. Dr. Evan is board-certified in Neurology, Clinical Neurophysiology and Epilepsy. Id.

ii. Expert Opinions

a. Petitioner's Expert, Dr. Klein[13]

Dr. Klein opined that petitioner's peripheral neuropathy and CTS were significantly aggravated due to a reaction to the flu vaccine that he received on October 2, 2015. Pet. Ex. 6. Dr. Klein differentiates petitioner's peripheral neuropathy and CTS as separate injuries that the flu vaccine exacerbated by direct and ongoing compression and inflammation of petitioner's left median nerve. Id. at 8.

1. Althen Prong One: Petitioner's Medical Theory

Dr. Klein began his report by discussing the two injuries at issue. He defined CTS as the

[13] Petitioner filed three expert reports authored by Dr. Klein. Pet. Exs. 6, 14, 19.

result of irritation and inflammation as the median nerve is compressed. Pet. Ex. 6 at 8. Dr. Klein next defined "peripheral neuropathy" as damage to the peripheral nerves of the body—the nerves outside the brain and spinal cord. Id. Peripheral nerves provide sensory input for touch, balance, temperature, and pain, and send signals to muscles to contract, which allows movement to occur. Id. Damage to peripheral nerves can result in abnormal signals, causing perception of pain or other abnormal sensations, such as numbness. Id.

With regard to his causal opinion, Dr. Klein stated that ecchymosis ("discoloration of the skin resulting from bleeding underneath typically caused by bruising") and "swelling can occur in any inflammatory state." Pet. Ex. 6 at 9. Inflammation increases the blood flow to an area of injury or infection, which can result in swelling. Id. Consequently, Dr. Klein opined that swelling in the carpal tunnel may increase pressure on the median nerve. Id. Additionally, Dr. Klein stated that swelling around fragile nerves, resulting from inflammation caused by a vaccine, can exacerbate any underlying pathology. Id.

As for the mechanistic cause of inflammation described above, Dr. Klein opined that petitioner's left shoulder vaccination resulted in dermatitis and "delayed immunologic hypersensitivity" and "prolonged inflammation due to a hypersensitivity reaction." Pet. Ex. 6 at 9; Pet. Ex. 14 at 3. Dr. Klein did not define or describe what he meant by hypersensitivity, or hypersensitivity reaction, or how either causes inflammation.

In regard to his theory of causation, Dr. Klein stated that "[w]hatever the ultimate cause of either condition, both peripheral neuropathy and carpal tunnel syndrome would be exacerbated by direct and/or ongoing compression of the affected nerve." Pet. Ex. 6 at 8.

Dr. Klein next addressed Dr. Evans comments on the improbability of a vaccination to trigger swelling. Dr. Klein cited Woo et al.[14] to support his opinion that limb swelling can occur due to vaccination. See Pet. Ex. 18. Woo et al. reviewed cases of extensive limb swelling occurring after vaccination reported to the Vaccine Adverse Event Reporting System ("VAERS"). Id. at 1. "Extensive limb swelling" was defined as "edema extending at least to the elbow or knee of a vaccinated extremity." Id. The authors identified 497 cases. Id. Generally, symptoms began within one day after vaccination and involved erythema, warmth, or pain. Id. at 1-2. Among the single limb and single vaccine cases, the most common associated vaccines included polyvalent pneumococcal, tetanus, diphtheria and pertussis, and flu. Id. at 3-4. There were approximately thirty reported cases of swelling associated with the flu vaccine. See id. at 4 fig.2. While the study supported Dr. Klein's assertion that the flu vaccine can cause limb swelling, it did not address the question of whether extensive limb swelling can cause or significantly aggravate CTS or peripheral neuropathy.

Further, the authors of the Woo et al. study recognized the limitations of using VAERS data and noted that incidence rates and relative risks cannot be calculated from the data. Pet. Ex. 18 at 5. The authors questioned whether extensive limb swelling "might be an exaggerated injection-site reaction." Id. at 6. Also, the authors concluded that extensive limb swelling after vaccination generally resolves without permanent sequelae. Id. at 7. There were no reports of

[14] Emily Jane Woo et al., Extensive Limb Swelling After Immunization: Reports to the Vaccine Adverse Event Reporting System, 37 Clinical Infectious Diseases 351 (2003).

permanent injury or disability.

2. Althen Prong Two: Logical Sequence of Cause and Effect

Dr. Klein next addressed logical sequence of cause and effect. He readily conceded that petitioner had "underlying carpal tunnel syndrome and peripheral neuropathy [] as a complication of diabetes," and that "his diabetes was not well controlled at the time of vaccination." Pet. Ex. 6 at 8. However, Dr. Klein opined that, "the vaccination more likely than not was a substantial causal factor in the development of the upper extremity inflammation and edema that resulted in worsening damage to the median nerve resulting in paresthesias, aching pain and discomfort, and weakness, in addition to the paresthesias of the radial nerve." Pet. Ex. 19 at 3. Dr. Klein did not describe what type of hypersensitivity reaction was at play, or how the alleged hypersensitivity reaction caused petitioner's inflammation and edema.

Dr. Klein did explain how diabetes causes peripheral neuropathy. He cited Yagihashi et al.[15] to explain how diabetes and elevated blood glucose acts as a poison to nerves over time. Pet. Ex. 12 at 1. The Yagihashi article states that diabetes is the most common cause of neuropathy due to the metabolic aberrations caused by diabetes which damage peripheral nerves. Id.

Dr. Klein then reviewed petitioner's medical history after he received the flu vaccination on October 2, 2015. Petitioner presented with dermatitis and skin eruption affecting his upper body, requiring an urgent care visit on October 8, 2015. Pet. Ex. 2 at 285-86. Subsequently, petitioner reported left arm numbness and tingling, and physical examination showed objective findings of dried scabs and ecchymoses of the left upper arm on March 19, 2016 by Dr. Kakehashi. Id. at 283-84. Neurological examination by Dr. Romine on March 28, 2016, was significant for "chemosis around the left deltoid region . . . [and] mild swelling of the left forearm." Id. at 262. Dr. Klein also observed that Dr. Kelso noted that petitioner appeared to have developed an inflammatory response to the immunization, perhaps including a delayed immunologic hypersensitivity. See Pet. Ex. 5 at 257; Pet. Ex. 6 at 9.

Based on the examinations performed by Dr. Kakehashi on March 19, 2016 and Dr. Romine on March 28, 2016, Dr. Klein opined that petitioner's left arm, from the shoulder to the wrist, was inflamed by the vaccine. Pet. Ex. 2 at 262, 283-84; Pet. Ex. 6 at 9. Dr. Klein stated that due to petitioner's diabetes, the affected nerves were more susceptible to additional injury. Pet. Ex. 6 at 9. Dr. Klein averred that also due to petitioner's older age, he was more susceptible to stress and deterioration than a healthy younger person individual. Id. Dr. Klein stated that additional edema and inflammation around a nerve, already subject to pathology, is highly dangerous for the health of the nerve. Id. He opined that, therefore, the swelling caused by the vaccination significantly exacerbated petitioner's existing peripheral neuropathy and CTS. Id.

In Dr. Klein's first supplemental expert report, he agreed with Dr. Evans, that a patient's complaints associated with a causal event should normally occur soon after the event in question.

[15] S. Yagihashi et al., Mechanism of Diabetic Neuropathy: Where Are We Now and Where to Go?, 2 J. Diabetes Investigation 18 (2010).

Pet. Ex. 14 at 1. However, he observed it is important to note that visits with providers are often problem focused, and "if patients do not provide added history because they are also focused on a more pressing issue at hand, then the other concerns will not be addressed and hence will not be documented by the treating physician." Id.

Dr. Klein also asserted that damage to the median nerve is often a slowly progressive problem. Pet. Ex. 14 at 2. Dr. Klein stated that even though petitioner may not have been experiencing the same amount of swelling and pain at the time of his March 19, 2016 visit to Dr. Kakehashi as he was when he first received the vaccination, the edema from the vaccine, over time, resulted in exacerbating damage to the median nerve. Id. Dr. Klein cited the article Werner et al.[16] to support his opinion that CTS has an asymptomatic latency period or a period when symptoms are noticeable, but not so severe that a patient will complain. Pet. Ex. 17.

In Werner et al., employees from various industrial industries were studied to determine whether asymptomatic workers with or without median nerve neuropathy developed symptoms consistent with CTS over an extended period of time, and what other factors influenced the onset of CTS symptoms. Pet. Ex. 17 at 2. The authors found that workers with an abnormal median nerve conduction test had an increased risk of developing CTS symptoms later in life than the group with normal nerve conduction findings. Id. at 5. The other risk factors for the development of CTS included older age, higher body mass index ("BMI"), and more repetitive work. Id. The Werner et al. study supports Dr. Klein's assertion CTS has a latency period. The study shows that at a follow-up of seventeen months, there was no increased risk of developing CTS symptoms based on initial nerve conduction findings. Id. However, at the seventy-month follow-up, participants did have an increased risk of developing CTS symptoms. Id.

Dr. Klein also cited Stevens et al.[17] to show that symptoms often begin at night and are initially considered insignificant by the patient. Pet. Ex. 16. Stevens evaluated the distribution of CTS symptoms in 100 patients with symptomatic, EMG verified, CTS, who had no other condition that might produce upper extremity symptoms. Id. at 1. The authors found there was a wide range of sensory symptoms deficits seen in CTS. Id. at 8. The study cited another article that reported CTS patients "insist[ed] that the whole hand gets numb and tingles at night." Id. at 4. The study therefore demonstrated some subjects with CTS have progressively worse symptoms over time.

Dr. Klein stated that the fact that petitioner's symptoms became clinically apparent in March 2016 does not mean that was the onset of the disease process. Pet. Ex. 14 at 2-3. Dr. Klein opined that in petitioner's case, the best way to account for the progression of his illness as reported in the medical records is to conclude that his October 2015 flu shot caused swelling that greatly exacerbated nerve damage, which subsequently manifested as clinically significant CTS. Id.

[16] R.A. Werner et al., Prolonged Median Sensory Latency as a Predictor of Future Carpal Tunnel Syndrome, 24 Muscle & Nerve 1462 (2001).

[17] J.C. Stevens et al., Symptoms of 100 Patients with Electromyographically Verified Carpal Tunnel Syndrome, 22 Muscle & Nerve 1448 (1999).

Lastly, Dr. Klein noted that petitioner continued to be symptomatic even after his carpal tunnel surgery on May 23, 2016. See Pet. Ex. 5 at 254-55; Pet. Ex. 6 at 10. Dr. Klein opined this was due to the existing damage noted on petitioner's EMG. Pet. Ex. 6 at 10. Dr. Klein also averred that Mr. Barlow's potential diagnosis of brachial neuritis, as referenced by Dr. Kelso, was not supported by the diagnostic studies performed. See Pet. Ex. 2 at 2; Pet. Ex. 6 at 9.

3. Althen Prong Three: Proximate Temporal Relationship

With regard to onset, Dr. Klein agreed there was a delay between the date of vaccination, October 8, 2015, and the date that petitioner's symptoms were first documented, March 28, 2016. Pet. Ex. 6 at 10. Based on his experience, however, Dr. Klein opined that it is not uncommon for patients like petitioner, who suffer from a variety of conditions, to treat one while foregoing treatment of another. Id. In particular, given that petitioner already suffered from diabetic neuropathy, Dr. Klein believed it was plausible for petitioner to prioritize treatment for his other problems over his neurological symptoms. Id. Beyond that, Dr. Klein found nothing in petitioner's records that gives any reason to doubt the accuracy of his report of exacerbation of neurologic symptoms beginning as early as several days following vaccination. Id.

Dr. Klein addressed Dr. Evans assertion that it was "implausible" for petitioner's physicians not to note Mr. Barlow's left arm complaints or physical signs earlier if they existed. Pet. Ex. 19 at 1. Dr. Klein asserted that it cannot be assumed that petitioner's primary care provider, Dr. Hougen, noted all of petitioner's signs and symptoms at Mr. Barlow's various appointments. Id. at 2. Dr. Klein then stated it is "unclear why Dr. Evans assumes that the cardiology [physician assistant] who treated Mr. Barlow's left leg skin pathologies would have noted any signs and symptoms in his left arm." Id.; see Pet. Ex. 2 at 34. Dr. Klein stated that Mr. Barlow's left leg issues were more pressing at that appointment, and the physician assistant was trained in cardiology, not dermatology or neurology. Pet. Ex. 19 at 2.

Additionally, Dr. Klein believed petitioner's left arm symptoms could have been overlooked because it is common for physicians to make diagnostic errors. Pet. Ex. 19 at 2. He cited the study by Schiff et al.[18] to support his argument that physician error is common. Pet. Ex. 20. Schiff et al. analyzed self-reported diagnostic errors by physicians and found that physicians rated 28% of these errors as "major." Id. at 3. The study also found that "drug reactions or overdose" were the second most commonly missed or delayed category of diagnosis. Id. Dr. Klein characterized petitioner's complications from vaccination as a "drug reaction." Pet. Ex. 19 at 2. The authors of the study concluded that, "[p]hysicians readily recalled multiple cases of diagnostic errors." Pet. Ex. 20 at 7. Based on the article's findings, Dr. Klein concluded that Dr. Evans' confidence in the ability of clinicians to note and respond to all relevant symptoms, including symptoms outside their specialties, is overly optimistic. Pet. Ex. 19 at 2.

Dr. Klein relied on the fact that Mr. Barlow's treating physicians appeared to accept petitioner's accounts regarding onset as accurate. Pet. Ex. 6 at 10. Dr. Klein opined that the close temporal association between vaccination and dermatitis/swelling, quickly followed by worsening of neurological symptoms as noted by Mr. Barlow's physicians, strengthens the case

[18] G.D. Schiff et al., Diagnostic Error in Medicine, 169 Archives Internal Med. 1881 (2009).

for a causal connection between the vaccine and the exacerbated pathologies. Id.

Further, Dr. Klein asserted that ongoing nerve damage may not result in clinical symptoms early on. He explained that a patient may not feel that his symptoms are significant until they reach a threshold, encouraging a patient to seek treatment. Pet. Ex. 14 at 2. Dr. Klein stated that there is some experimental evidence from Ibrahim et al. that the severity of neural dysfunction in the carpal tunnel is directly correlated with the duration and severity of pressure on the median nerve. Id.; see Pet. Ex. 15. This suggests that, all other things being equal, aggravation of carpal tunnel symptoms by vaccine-induced inflammation and swelling would become more severe over time. Pet. Ex. 14 at 2. Dr. Klein concluded that after vaccination, Mr. Barlow may have found his symptoms harder to ignore as time went on. Id.

Dr. Klein stated that "[n]either Dr. Evans nor I was present when Dr. Kakehashi examined Mr. Barlow on 3/19/16, so the best that we can do is to carefully assess Dr. Kakehashi's physician notes." Pet. Ex. 14 at 2. Dr. Klein provided that because neither of the experts examined petitioner, they should defer to Dr. Kakehashi's apparent acceptance of petitioner's account of onset. Id. Moreover, Dr. Klein opined there is no clear reason why Mr. Barlow would have stated that his symptoms started over five months before they actually did. Id.

Dr. Klein then questioned Dr. Evans' skepticism of Dr. Kakehashi's acceptance of petitioner's onset history. A doctor's decision, opined Dr. Klein, is "to accept the history given by a patient based on his or her considered professional judgment." Pet. Ex. 14 at 3. If one accepts the history given by petitioner to Dr. Kakehashi, Dr. Klein believes that "the most reasonable interpretation" of the medical records is that petitioner had "latent carpal tunnel syndrome, either secondary to diabetes or independently of it, and that this condition was exacerbated by edematous swelling in response to vaccination." Id. Dr. Klein opined that petitioner's condition would have gotten worse over time, and it is possible that Mr. Barlow's CTS would have eventually become clinical even in the absence of vaccination, but given the swelling following vaccination, it is highly likely that the vaccine accelerated the process. Id.

b. Respondent's Expert, Dr. Evans[19]

1. Althen Prong One: Respondent's Medical Theory

Dr. Evans disagrees with Dr. Klein's proposed mechanism that swelling of the left arm following a flu vaccination can cause and/or exacerbate CTS and peripheral neuropathy for four reasons. First, in order to develop CTS and/or peripheral neuropathy secondary to limb edema, Dr. Evans opines that the limb swelling must be severe. Resp. Ex. A at 10-11. Second, the resulting CTS or neuropathy must be acute and not chronic in nature, as a reflection of the proposed mechanism. Id. Third, the flu vaccine has not been implicated as causally related to these conditions. Id. And fourth, CTS and peripheral neuropathy are associated with diabetes, and therefore, it is not necessary to invoke a vaccine-related cause here. Resp. Ex. C at 2.

As for the first principal, Dr. Evans agreed that Dr. Klein's theory could be true in cases

[19] Respondent filed two expert reports authored by Dr. Evans. Resp. Exs. A, C.

of "compartment syndrome." Resp. Ex. A at 10-11. In compartment syndrome, pressure in an anatomic compartment (i.e., forearm) is increased to levels that harm neural, muscular, or vascular elements within the compartment. Id. Compartment syndrome, however, is a medical emergency, and the pain associated with it is severe. See Resp. Ex. A-10 at 2.

To illustrate this point, Dr. Evans cited to a case report by Mohamed Ali Sbai et al.[20] Resp. Ex. A-10. In the case report, a patient presented to the Emergency Department with extreme pain, swelling, and inability to move her fingers. Id. at 2. The patient was taken into surgery immediately. Id. Dr. Evans used the report to show that compartment syndrome is an acute emergency, and not a condition that could occur over a period of weeks, or longer, and it is unlikely that a physician would fail to document its signs and symptoms. Id.

Dr. Evans conceded that other edematous conditions, such as those created by burns,[21] pregnancy,[22] and post-mastectomy lymphedema,[23] have also been reported to cause CTS and other neuropathies. Resp. Ex. A at 11. However, again, Dr. Evans explained that those conditions manifest significant trauma and edema, resulting in nerve damage associated with CTS. Id.

Secondly, Dr. Evans explained that compartment syndrome, and other edematous conditions causally associated with CTS, are more acute, instead of chronic, in nature. In support of this aspect of his opinion, Dr. Evans cited Tosti and Ilyas.[24] Resp. Ex. A-11. The authors define acute CTS as "rapid onset of median neuropathy caused by sudden increases in carpal tunnel pressures, which leads to ischemia of the median nerve. The most common cause is traumatic injury, although atraumatic sources should also be recognized." Id. at 2. Traumatic injuries include fractures, lacerations, burns, animal bites, and high-pressure injection injuries. Id. Rare atraumatic sources listed in the article include edematous states that raise intracanal pressures, for example, "pregnancy, burns, venom and toxins, and pancreatic transplant recipients." Id. The Tosti and Ilyas article does not identify vaccinations as a cause of CTS.

The third basis for Dr. Evans' opinion is that CTS has only rarely been reported

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[20] Mohamed Ali Sbai et al., Acute Carpal Tunnel Syndrome of the Hand Following a Cat Bite, 21 Pan African Med. J. 206 (2015).

[21] See C. Balakrishnan et al., Acute Carpal Tunnel Syndrome from Burns of the Hand and Wrist, 17 Can. J. Plastic Surgery e33 (2009).

[22] M. Breborowicz et al., Symptomatology of Carpal Tunnel Syndrome During Pregnancy and Puerperium, 84 Ginekologia Polska 841 (2013). Respondent provided the abstract because the full text was in Polish.

[23] A. Ganel et al., Nerve Entrapments Associated with Postmastectomy Lymphedema, 44 Cancer 2254 (1979).

[24] R. Tosti & A.M. Ilyas, Acute Carpal Tunnel Syndrome, 43 Orthopedic Clinics North Am. 459 (2012).

following any vaccinations. Resp. Ex. A at 10. In Janier et al.,[25] CTS occurred after accidental injection of BCG vaccine into the wrist. Resp. Ex. A-8. Thus, the Janier et al. case presents a different factual scenario than shoulder vaccination. Id. Ray et al.[26] reported that rubella vaccination may be associated with a small risk of chronic arthropathy, which in turn has been associated with CTS. Resp. Ex. A-9 at 1. Similarly, Hale and Ruderman[27] detailed a case of CTS onset six weeks after rubella vaccination. Resp. Ex. A-6. The subject noted stiffness in her hands and swelling of her joints three weeks after vaccination. Id. at 1. Six weeks after vaccination, doctors noted swelling, redness, and warmth of her wrist. Id. After treatment, her symptoms disappeared. Id. at 3-4. None of the case reports implicate Dr. Klein's theory of post-vaccination hypersensitivity inflammation and edema as causal mechanism for CTS.

Dr. Evans' fourth reason for disagreeing with Dr. Klein's mechanism is that CTS is an exceedingly common condition, especially in patients who have diabetes. See Resp. Ex. A at 10. Therefore, it is not necessary to invoke the flu vaccine as a cause in a patient with diabetes and pre-existing peripheral neuropathy.

In support of this opinion, Dr. Evans cites Gamstedt et al,[28] in which the authors reported rates of CTS up to 20% in patients with diabetes. Resp. Ex. A-4 at 1. The Gamstedt article investigated the prevalence of CTS in patients with diabetes mellitus and the association between the hand abnormalities and diabetic variables. Id. The study postulated that increased glycosylation of proteins,[29] diabetic microangiopathy, and diabetic neuropathy are the mechanisms that can cause CTS in diabetic patients. Id. at 4-5.

2. Althen Prong Two: Logical Sequence of Cause and Effect

Dr. Evans agrees with petitioner's expert, Dr. Klein, as to petitioner's diagnoses of CTS and peripheral neuropathy, but does not believe that petitioner's flu vaccine caused or exacerbated his conditions.

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[25] M. Janier et al., Carpal Tunnel Syndrome Due to Mycobacterium Bovis BCG, 58 Sem Hop. 977 (1982) (author's transl.). The full text was not available, and only the abstract was filed with the Court. The BCG vaccine is typically used to vaccinate against tuberculosis.

[26] P. Ray et al., Risk of Chronic Arthropathy Among Women After Rubella Vaccination, 278 JAMA 551 (1977).

[27] M.S. Hale & J.E. Ruderman, Carpal Tunnel Syndrome Associated with Rubella Immunization, 52 Am. J. Physical Med. 189 (1973).

[28] A. Gamstedt et al., Hand Abnormalities are Strongly Associated with the Duration of Diabetes Mellitus, 234 J. Internal Med. 189 (1973).

[29] A glycosyl is the radical formed from a saccharide and glycosylation is the linkage of glycosyl groups. Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=20670&searchterm=glycosylation (last accessed July 14, 2020).

Dr. Evans agreed with Dr. Romine's diagnosis of March 19, 2016, finding left median neuropathy and CTS. Resp. Ex. A at 9; Pet. Ex. 5 at 19-20. An EMG/NCV showed definitive evidence supporting the diagnosis of severe, chronic left median neuropathy consistent with the diagnosis of CTS, along with mild sensorimotor neuropathy of the type usually associated with diabetes mellitus. Resp. Ex. A at 9. Dr. Evans also agreed with Dr. Klein that the diagnosis of brachial neuritis is not supported. Id.

While Dr. Evans agreed that severe swelling can exacerbate CTS, he does not believe that Mr. Barlow's swelling was sufficient to cause the condition. Resp. Ex. C at 2. Dr. Evans stated that the fact that none of the medical practitioners petitioner visited between the date of his vaccination and the date that he first complained of symptoms, over five months later, ever observed any significant swelling in Mr. Barlow's arm is evidence that the swelling was insufficient to cause injury. Id. If severe swelling had occurred, Dr. Evans would have expected petitioner to report it and his physicians to document it. Id.

Dr. Evans also disagreed with Dr. Klein's statement that the experts should "defer to Dr. Kakehashi's impression" of petitioner's injury. Resp. Ex. C at 1. Dr. Evans opined that Dr. Kakehashi did not observe the swelling, weeping, and ecchymoses that reportedly occurred after vaccination, he only recorded what the patient told him. Id. at 1-2. Further, Dr. Evans found that Mr. Barlow's own medical record contradicts his report to Dr. Kakehashi. Id. at 1. To demonstrate this, Dr. Evans pointed to the Urgent Care visit six days after vaccination. Pet. Ex. 2 at 285; Pet. Ex. 5 at 296-302. At that appointment, petitioner complained of dermatitis of the shoulders, chest, and lower back. Pet. Ex. 2 at 285-86. However, during that visit there was no note of symptoms in the left arm or forearm, and specifically no note of swelling.

Next, Dr. Evans noted that Mr. Barlow visited his dermatologist 53 days after vaccination. Pet. Ex. 5 at 63. At this visit, lesions on the face and left leg were noted, but there was no indication of swelling or other symptoms in the left arm. Id. Mr. Barlow also had two visits to his cardiology physician assistant for treatment of left leg cellulitis, two visits to the office of his primary care internist, and two visits to his podiatrist, and none recorded a complaint or physical sign related to the left arm. Resp. Ex. C at 1-2; Pet. Ex. 2 at 8-27, 34, 38; Pet. Ex. 5 at 45, 54-62, 66, 70-74.

Dr. Klein attributed the absence of recorded complaints about petitioner's alleged symptoms of CTS by his practitioners to be due to the "problem-focused" nature of the visits. See Resp. Ex. C at 2. Dr. Evans found that to be plausible in the case of the podiatry visits, in which both the physician and patient would expect only foot complaints to be relevant, but unlikely for the other visits. Id. Dr. Evans opined, "it is implausible for visits to his primary internist and dermatologist, and implausible also for the cardiology [physician's assistant] who treated his left leg cellulitis with edema and stasis dermatitis—any of these practitioners would be expected to note if the patient had left arm complaints or if there were significant left arm physical signs." Id. Dr. Evans stated that the practitioners may defer action on the problem, or refer to another practitioner for treatment, but they would not ignore it. Id. Dr. Evans found it especially unlikely for petitioner's visit to his dermatologist, who noted spots on his cheek and spots on his leg, to have failed to record severe dermatological signs and symptoms in the left

arm. Id. Dr. Evans believed, therefore, that the medical records contradict Mr. Barlow's recollection of events as documented by Dr. Kakehashi, so long (169 days) after vaccination. Id.

Further, Dr. Evans opined that Mr. Barlow's peripheral neuropathy and CTS were chronic conditions, and not acute, and therefore, inconsistent with cases reported as associated with vaccination. Resp. Ex. A at 11. On April 19, 2016, Dr. Romine opined petitioner had chronic neurogenic changes consistent with entrapment of the median nerve. Pet. Ex. 5 at 523. On April 21, 2016, petitioner's orthopedist Dr. Hamer diagnosed petitioner with left severe chronic CTS. Id. at 259. Chronic neuropathy and chronic CTS are identified as active problems in petitioner's medical record. See Pet. Ex. 13 at 11. Because petitioner's peripheral neuropathy and CTS were diagnosed as chronic and not acute, by both his orthopedist and neurologist, his clinical course is different than the case reported by Tosti and Ilyas. See Resp. Ex. A-11 at 2. In summary, Dr. Evans asserted the flu vaccination did not create a sufficiently edematous condition enough to cause acute increased pressure within petitioner's carpal tunnel. Resp. Ex. A at 11. If it had, it would have been reported at petitioner's Urgent Care visit six days after vaccination. See Resp. Ex. C at 2.

Next, Dr. Evans found that the medical literature did not support a causal connection between the flu vaccine and CTS. He explained that the literature demonstrates a different clinical course than what Mr. Barlow experienced. See Resp. Ex. A at 10. Petitioner did not have injection or trauma at the wrist. For example, in Janier et al., the subject received an injection into her wrist, whereas petitioner was vaccinated in his shoulder. Resp. Ex. A-8. Ray et al. reported that the rubella vaccination may be associated with a small risk of chronic arthropathy, which in turn has been associated with CTS. Resp. Ex. A-9 at 1. Petitioner was not diagnosed with wrist arthropathy prior to his CTS, and Dr. Klein does not offer that mechanism here. Additionally, in the Hale and Ruderman's case report, the patient's symptoms resolved after treatment. Resp. Ex. A-6 at 3-4. Here, Mr. Barlow's CTS symptoms never resolved.

Dr. Evans opined the most likely cause of the exacerbation of petitioner's CTS and peripheral neuropathy was his diabetes. Resp. Ex. C at 2. Dr. Evans averred "that a risk factor for carpal tunnel syndrome in Mr. Barlow's case is diabetes. I would go further to state that it is the only documented risk factor." Id. Dr. Evans referred to Gamstedt et al. to show CTS "is an exceedingly common condition" in patients with diabetes. Resp. Ex. A at 10; Resp. Ex. A-4. According to the medical records submitted by petitioner, petitioner had uncontrolled diabetes since 2011. See Pet. Ex. 3 at 784. Petitioner's expert also conceded that petitioner's diabetes was not well controlled at the time of vaccination. Pet. Ex. 6 at 9.

3. Althen Prong Three: Proximate Temporal Relationship

As stated above, Dr. Evans found the fact that Mr. Barlow had no documented complaints about his vaccinated left arm until March 19, 2016—about five-and-one-half months after his vaccination—despite having many visits to various medical providers, implausible. Resp. Ex. A at 8-9. Between petitioner's vaccination on October 2, 2015 and the first report of left arm symptoms almost six months later, Mr. Barlow had eight documented visits to medical providers, including to his long-time internist Dr. Hougen. Id. at 9. None of these medical

providers documented the left arm problems, and none of them documented any problems related to the vaccination. Id.

Dr. Evans opined that if left arm swelling occurred as later-in-time reported by petitioner, it occurred with such a long delay as to make a relationship to vaccination very unlikely, and persisted for such a short period of time that injury to the median nerve would likewise be unlikely. Resp. Ex. A at 11. In summary, Dr. Evans stated that although the records show that petitioner had CTS, they also make it clear that his vaccination was unlikely to have caused or exacerbated his condition. Id.

V. LEGAL FRAMEWORK AND ANALYSIS

A. Standards for Adjudication—Causation

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

B. Causation Theory

To receive compensation under the Program, petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because petitioner does not allege that he suffered a Table injury, he must prove that the vaccine caused his illness. To do so, he must establish, by preponderant evidence: (1) a medical

theory causally connecting the vaccine and his injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and his injury ("Althen Prong Three"). § 13(a)(1); Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Thus, petitioner must provide a reputable medical or scientific explanation for his theory, although the explanation need only be "legally probable, not medically or scientifically certain," it must be "sound and reliable." Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1360 (Fed. Cir. 2019); Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on assertions. Rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material contained in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' offered experts and rule in petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

i. Law Governing Analysis of Fact Evidence

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (noting it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993); Doe/70 v. Sec'y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010) ("Given the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law."); Rickett v. Sec'y of Health & Hum. Servs., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick

people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), vacated, on other grounds, 809 F. App'x 843 (Fed. Cir. 2020); see also Cucuras, 993 F.2d at 1528.

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. Cucuras, 993 F.2d at 1528; see also Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." (citing United States v. U.S. Gypsum Co., 333 U.S. 364, 396 (1947)), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie, 2005 WL 6117475, at *19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

ii. Evaluation of Expert Testimony

Another important aspect of the causation-in-fact case law under the Vaccine Act concerns the factors that a special master may consider in evaluating the reliability of expert testimony and other scientific evidence. In Daubert v. Merrell Dow Pharmaceutical, Inc., the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. 509 U.S. 579 (1993). In Terran v. Secretary of Health & Hum. Services, the Federal Circuit ruled that it is appropriate for special masters to utilize the Daubert factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases. 195 F.3d 1302, 1316 (Fed. Cir. 1999).

Daubert instructs fact-finders to consider:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general

acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing Daubert, 509 U.S. at 592-95). In addition, where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the ipse dixit of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 743 (2009) (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)).

A treating physician's opinions are considered "quite probative," as treating physicians are in the "best position" to evaluate the vaccinee's condition. Capizzano, 440 F.3d at 1326. However, no treating physician's views bind the special master, per se; rather, their views should be carefully considered and evaluated. § 13(b)(1); Snyder, 88 Fed. Cl. at 745 n.67. Each opinion from a treating physician should be weighed against other, contrary evidence present in the record—including conflicting opinions from other treating physicians. Hibbard v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 742, 749 (Fed. Cl. 2011), aff'd, 698 F.3d 1355 (Fed. Cir. 2012); Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 136 (2011), aff'd, 463 F. App'x 932 (Fed. Cir. 2012); Veryzer v. Sec'y of Health & Hum. Servs., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), mot. for rev. denied, 100 Fed. Cl. 344 (2011).

iii. Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, including some articles that do not weigh heavily on the outcome herein. The undersigned has reviewed and considered all of the medical literature submitted in this case, though the undersigned only discusses those articles that are most relevant to entitlement and/or are central to petitioner's case—just as the undersigned has not exhaustively discussed every individual medical record filed. Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision."); see also Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

C. Analysis

i. Althen Prong One: Petitioner's Medical Theory

Under Althen Prong One, petitioner must set forth a medical theory explaining how the flu vaccination can cause significant aggravation of peripheral neuropathy and CTS. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. The theory of causation must be informed by a reputable medical or scientific explanation, although the explanation need only be "legally probable, not medically or scientifically certain," it must be "sound and reliable." Boatmon, 941

F.3d at 1359; Knudsen, 35 F.3d at 548-49; see also Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 300aa-13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) ("Expert opinion is no better than the soundness of the reasons supporting it." (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

This case presents an alleged novel injury in the Vaccine Program—CTS following flu vaccination in the shoulder.[30] Petitioner's causal theory is that the flu vaccine, administered in the left shoulder, caused "prolonged inflammation due to a hypersensitivity reaction" and/or a "delayed immunologic hypersensitivity" reaction. Pet. Ex. 6 at 9. However, Dr. Klein fails to define or describe "hypersensitivity reaction" or how it causes inflammation.

Dorland's defines hypersensitivity as "a state of altered reactivity in which the body reacts with an exaggerated or inappropriate immune response to what is perceived to be a foreign substance." Dorland's Illustrated Medical Dictionary 884 (33d ed. 2020). Hypersensitivity reactions are classified as types I to IV. Type I hypersensitivity occurs "within minutes" of exposure and the symptoms can range from a localized rash to systemic anaphylaxis. Id. at 1574. Type II hypersensitivity causes tissue or cell damage due to the "interaction of antibodies and antigens on cell surfaces." Id. at 1575. A transfusion reaction is an example of type II hypersensitivity. Id. Type III is a "local or general inflammatory response due to formation of circulating antigen-antibody complexes and their deposition in tissues," often referred to as immune complex-mediated hypersensitivity. Id. An example is "systemic lupus erythematosus." Id. And type IV is an "immune response [] initiated by antigen-specific T lymphocytes," also called "cell-mediated immunity or T cell-mediated hypersensitivity." Id.

[30] A Decision on Joint Stipulation was issued in 2014, in McCray v. Secretary of Health & Hum. Services, where petitioner alleged flu vaccine caused brachial neuritis, and/or complex regional pain syndrome, and/or CTS. No. 11-567V, 2014 WL 2920799 (Fed. Cl. Spec. Mstr. June 2, 2014). However, the McCray petitioner, unlike Mr. Barlow, alleged two alternative injuries, brachial neuritis and complex regional pain syndrome. Brachial neuritis is a Table Injury for vaccines that contain tetanus toxoid, and has also been seen in the context of other vaccines. See 42 C.F.R. § 100.3(c)(6); Greene v. Sec'y of Health & Hum. Servs., No. 11-631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019), mot. for rev. denied, 146 Fed. Cl. 655 (2020); McNorton v. Sec'y of Health & Hum. Servs., No. 13-35V, 2014 WL 6704500, at *1 (Fed. Cl. Spec. Mstr. Nov. 4, 2014); Ebbs v. Sec'y of Health & Hum. Servs., No. 18-0260V, 2020 WL 1488640 (Fed. Cl. Spec. Mstr. Feb. 18, 2020). Post-vaccination complex regional pain syndrome has also been the subject of vaccine cases following various vaccines. See Dixon-Jones v. Sec'y of Health & Hum. Servs., No. 14-934V, 2019 WL 7556374 (Fed. Cl. Spec. Mstr. Sept. 4, 2019); Lusk v. Sec'y of Health & Hum. Servs., No. 15-1190V, 2016 WL 2616997 (Fed. Cl. Spec. Mstr. Jan. 28, 2016).

Here, petitioner did not identify the type of hypersensitivity, describe the process by which hypersensitivity can cause inflammation and/or injury to the median nerve, or offer any literature or other evidence to support this fundamental aspect of the proffered causal theory. Given that hypersensitivity reactions are varied and complex, a conclusory theory is insufficient. Specifically, petitioner did not explain how an immunization in the shoulder caused a hypersensitivity reaction resulting in inflammation and swelling of the structures in the carpal tunnel and injury to the median nerve so as to cause or aggravate petitioner's pre-existing CTS. See Pet. Ex. 6 at 9; Pet. Ex. 14 at 3. According to petitioner, this same theory of swelling and compression also aggravated his pre-existing peripheral neuropathy in his left upper extremity.

Respondent's expert, Dr. Evans, agrees that CTS and peripheral neuropathy can result from conditions that cause significant edema, including compartment syndrome, or edematous conditions caused by trauma, burns, pregnancy, or postmastectomy lymphedema. However, Dr. Evans disagrees that vaccination can lead to the alleged conditions here without evidence to support the type of edema or swelling associated with the conditions described above.

Balakrishnan et al. explains the mechanism whereby compartment syndrome can cause carpal tunnel syndrome. See Resp. Ex. A-1. Compartment syndrome occurs when the pressure within a compartment is increased to the point that there is vascular compromise of the structures within a compartment. Id. at 1. Hypoxia and ischemia of the microcirculation occurs. Id. at 2. "When intracarpal canal interstitial pressure rise above a critical threshold pressure capillary blood flow is reduced below the level required for median nerve viability." Id. Further, the sequence of events that lead to CTS, and vascular compromise described in the medical literature, is generally described as painful. Id. In case reports, the patients who developed CTS secondary to edema sought medical attention due to the severity of their pain.

While the Woo et al. article supports Dr. Klein's assertion that limb swelling can occur after vaccination, it did not address the issue of whether limb edema can cause or significantly aggravate CTS or peripheral neuropathy. See Pet. Ex. 18. The authors did not address Dr. Klein's mechanistic theory. Moreover, in Woo, the authors reported that extensive limb swelling after vaccination generally resolves without permanent injury or disability. Id. at 3.

Petitioner cited a number of other medical articles, but none of them provide support for Dr. Klein's opinion that a vaccine given in the deltoid muscle of the upper arm can result in swelling within the carpal tunnel so as to cause compression of the median nerve. And none of the articles describe a hypersensitivity reaction that results in CTS or peripheral neuropathy.

The National Institutes of Health article on CTS provides an overview of factors that can cause swelling of the wrist.[31] Pet. Ex. 8. Notably, these risk factors include trauma or injury directly to the wrist. See id. at 1. The article does not identify vaccination as a risk factor. The Ibrahim article provides a review of recent literature, and the authors conclude that CTS is a common condition. Pet. Ex. 9 at 1. Vaccination is not discussed as a risk factor or cause. In

[31] Nat'l Inst. of Neurological Disorders & Stroke, Carpal Tunnel Syndrome Fact Sheet, https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Carpal-Tunnel-Syndrome-Fact-Sheet (last modified Apr. 7, 2020).

Fullerton,[32] ischemia of the median nerve was studied, but again, there was no reference to vaccinations. See Pet. Ex. 10. And in Werner, the risk factors identified included older age and higher BMI, but swelling due to vaccination was not identified. See Pet. Ex. 17. None of these articles addressed swelling or nerve compression caused by a hypersensitivity reaction.

Similarly, the medical literature about peripheral neuropathy fails to identify vaccination or post-vaccination inflammation as a cause or risk factor. Diabetes is the leading cause, and 60-70% of diabetics have mild to severe peripheral neuropathy.[33] Pet. Ex. 11 at 3. Yagihashi et al. describes the mechanics of diabetic neuropathy. See Pet. Ex. 12. Swelling due to vaccination is not discussed. The Stevens et al. study cited by petitioner makes no mention of vaccination as a risk factor or cause of peripheral neuropathy. See Pet. Ex. 16.

CTS has been reported following vaccination, but the case reports do not support the causal mechanism posited by Dr. Klein. Several of the case reports describe CTS following rubella vaccination.[34] The rubella vaccine is a live attenuated virus vaccine, unlike the flu vaccine. The vaccine recipients had arthropathy, with stiffness and swelling of the hands and joints, and/or "marked synovial swelling over [the] wrists." Resp. Ex. A-6 at 1. The mechanism in the rubella vaccination cases is thought to be a "viral induced tenosynovitis." Id. at 5. In the Dyro[35] case report, the vaccine developed a mononeuropathy of the left radial nerve affecting muscle in the left arm and wrist following the New Jersey/76 Swine Flu vaccination. Resp. Ex. A-3. The median nerve was not affected. See id. None of these cases implicate Dr. Klein's theory of hypersensitivity reaction leading to inflammation as the mechanism of CTS.

When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. denied, 141 Fed. Cl. 138 (2018), aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. See id.

In summary, petitioner has not offered a sound and reliable medical theory in support of his claim. Petitioner has not met the preponderant evidentiary standard with respect to the first Althen prong.

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[32] P.M. Fullerton, The Effect of Ischemia on Nerve Conduction in the Carpal Tunnel Syndrome, 26 J. Neurology Neurosurgery Psychiatry 385 (1963).

[33] Nat'l Inst. of Neurological Disorders & Stroke, Peripheral Neuropathy Fact Sheet, https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Peripheral-Neuropathy-Fact-Sheet (last modified Mar. 16, 2020).

[34] See Resp. Ex. A-9; Resp. Ex. A-6.

[35] F. M. Dyro, Vaccination Mononeuropathy, 3 Annals Neurology 468 (1978).

ii. Althen Prong Two: Logical Sequence of Cause and Effect

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). Petitioner must show "that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (citations omitted).

Since petitioner has failed to prove Althen Prong One, it follows that he cannot prove Althen Prong Two. However, even if petitioner had proven a sound and reliable causal mechanism, he has failed to prove by preponderant evidence a logical sequence of cause and effect, showing his flu vaccine caused or significantly aggravated his CTS and peripheral neuropathy for three reasons. First, petitioner failed to show that the proposed causal theory is consistent with his clinical course. Second, petitioner's treating physicians' records and opinions do not support vaccine causation, and third, Dr. Evans' opinions are more persuasive.[36]

As for the first reason, petitioner, through his expert, fails to explain or show that his clinical course was consistent with a hypersensitivity reaction induced inflammation that aggravated petitioner's CTS or peripheral neuropathy. Dr. Klein does not point to any diagnostic tests, any facts, or any other evidence to show that petitioner's CTS or peripheral neuropathy occurred due to a hypersensitivity reaction.

Dr. Klein asserts that petitioner's flu vaccination caused a "cascade of clinical concerns, beginning with [] dermatitis and skin eruption." Pet. Ex. 6 at 9. Petitioner was diagnosed with dermatitis shortly after receipt of his flu vaccine, but neither he nor the Urgent Care physician who treated him attributed it to the flu vaccine or a hypersensitivity reaction caused by the vaccine. Specifically, petitioner told Dr. Henderson that he had a history of sensitive skin and thought the rash was due to a change in detergent. Pet. Ex. 2 at 286. Dr. Henderson concluded that petitioner's dermatitis was due to "some type of exposure." Id. In context, this reference relates to petitioner's history of sensitive skin and belief that his dermatitis was due to detergent exposure. Dr. Henderson did not suggest that petitioner's dermatitis was caused by the flu vaccine.

Moving forward, more than five months later, Dr. Kakehashi documented a residual halo from bruises of the deltoid (upper arm), but did not document any hypersensitivity reaction, or inflammation or swelling. Notably, Dr. Kakehashi did not document any history or physical finding to suggest that petitioner's left arm from the shoulder to the wrist had been or was inflamed. When seen by Dr. Romine on March 28, 2016, petitioner reported that his "whole arm turned purple, but over time this resolved." Pet. Ex. 2 at 262. Dr. Romine noted "mild swelling"

[36] In his Memorandum, petitioner agrees that while both Dr. Klein and Dr. Evans are qualified to give expert opinions in this matter, that Dr. Klein is "better suited" because his CV shows that he has expertise in electrodiagnostic and neuromuscular conditions. Pet. Mot. at 8. The undersigned agrees that both experts are qualified, and acknowledges Dr. Klein's subspecialty and professional associations. However, given all of the evidence here, the undersigned finds Dr. Evans' opinions more persuasive for all of the reasons stated.

of petitioner's forearm. Id. But Dr. Romine did not document any history or physical finding that petitioner's left arm, from his shoulder to his wrist, was inflamed. There is no factual support in the contemporaneous medical records that petitioner's dermatitis triggered a "cascade of concerns" or hypersensitivity reaction that played a role in causing or significantly aggravating petitioner's CTS or peripheral neuropathy. To the extent that hypersensitivity is referenced, it is in regard to petitioner's dermatitis, not his CTS or peripheral neuropathy.

Secondly, a careful review of the medical records reveals that the medical records and opinions of the treating physicians do not support vaccine causation. The first time that petitioner attributes any problem to his flu vaccine was March 19, 2016, when he was seen at Urgent Care for pain and left arm paresthesias. Pet. Ex. 2 at 283. Dr. Kakehashi's assessment was "left arm paresthesias since receiving the flu vaccination." Id. Other than noting the temporal association, Dr. Kakehashi did not opine that the flu vaccine caused petitioner's pain or paresthesias. In fact, Dr. Kakehashi did not reach a diagnosis, but referred petitioner to a neurologist.

Subsequently, petitioner was seen by neurologist, Dr. Romine, on March 28, 2016, who made two diagnoses: "1. Status post remote flu immunization (October 2015); local reaction with ecchymosis and swelling of the left upper extremity, improved. 2. Probable left carpal tunnel syndrome; possible left radial, sensory cutaneous neuropathy." Pet. Ex. 2 at 262. While Dr. Romine did diagnosis a vaccine related local reaction, his diagnoses of CTS and possible radial neuropathy were enumerated separately and not described as causally related to vaccination.

One year later, on March 21, 2017, Dr. Romine made the following diagnoses: "1. Status post left carpal tunnel release – persistent numbness of hand . . . [and] forearm – localization/cause unclear. 2. Persistent numbness and sensory deficit of left forearm and hand status post remote flu shot -? possible residual post immunization brachial neuritis?" Pet. Ex. 5 at 20.

Dr. Romine did not attribute petitioner's CTS to his flu vaccine, but stated that the cause was unclear. As for petitioner's numbness and sensory deficient, Dr. Romine only believed that vaccine causation was "possible." An opinion expressed as a possibility is insufficient to establish causation.[37]

[37] See LaCour v. Sec'y of Health & Hum. Servs., No. 90-316V, 1991 WL 66579, at *5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991) ("Expert medical testimony which merely expresses the possibility—not the probability—of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred."); Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard); De Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008) (finding that while certainty is by no means required, a possible mechanism does not rise to the level of preponderance); see also Dobrydnev v. Sec'y of Health & Hum. Servs., 566 F. App'x 976, 981 (Fed. Cir. 2014).

Petitioner later saw immunologist Dr. Kelso, who made two diagnoses. Dr. Kelso stated:

> Neuromuscular and dermatologic abnormalities following influenza vaccination. The neuromuscular abnormalities may represent brachial neuritis which has been described after injections of vaccines . . . and is thought to represent an inflammatory response around nerves and/or be related to the trauma of the injection itself. The dermatologic abnormalities are not typically reported in association with brachial neuritis but could also represent an inflammatory response to the immunization perhaps including a delayed immunologic hypersensitivity.

Pet. Ex. 2 at 2; Pet. Ex. 5 at 257.

This note shows that Dr. Kelso described two conditions with two respective causal mechanisms. He stated that brachial neuritis following vaccination may be due to an inflammatory response around the nerves or direct trauma from injection. He did not suggest that brachial neuritis was caused by a hypersensitivity reaction. Dr. Kelso's reference to post-vaccination hypersensitivity reaction relates to dermatitis, not CTS or peripheral neuropathy. Further, Dr. Kelso did not diagnose petitioner with CTS. And he did not attribute petitioner's CTS or peripheral neuropathy to the dermatological condition (dermatitis).

In summary, when Dr. Klein describes a "cascade of concerns," he conflates two different mechanisms described by Dr. Kelso, attributing both CTS and peripheral neuropathy to a hypersensitivity reaction. But this interpretation is not supported by Dr. Kelso's note, the evidence, Dr. Klein, or the medical literature.

At the petitioner's request, Dr. Hougen reviewed "both peripheral neuropathy and median neuropathy [CTS]" with the petitioner. Pet. Ex. 2 at 247. Dr. Hougen noted that petitioner's peripheral neuropathy was consistent with his diabetes. And Dr. Hougen explained that petitioner's EMG showed "median nerve entrapment at the carpal tunnel." Id. Dr. Hougen did not opine that either condition was caused by the petitioner's flu vaccine.

Therefore, the undersigned finds that none of petitioner's treating physicians opined that the flu vaccine caused or aggravated his CTS or peripheral neuropathy.

Third, the undersigned finds Dr. Evans' opinions regarding petitioner's clinical course to be more persuasive because they are more consistent with the findings and conclusions of petitioner's treating physicians documented in the contemporaneous medical records. Excluding his visits to a podiatrist,[38] petitioner saw four different health care providers six times in a three-month period immediately following vaccination. All four of these providers performed and documented independent physical examinations of petitioner. During the six different visits, petitioner had varied and specific complaints. His complaints were well described and documented each visit. The four different providers included an urgent care physician, a

[38] A podiatrist specializes in the care and treatment of the foot, and as such, would not be expected to perform an evaluation of the upper extremities. For a definition of podiatrist, see Dorland's at 1455.

longstanding primary care physician, a cardiology physician assistant, and a dermatologist. While Dr. Klein may be correct that physicians make errors, it would be quite a stretch to assume that all four of these health care providers repeatedly failed to properly take or document a history, or failed to perform or document an accurate physical examination. The undersigned will not base her decision on allegations of improper medical care where there is no evidence of such, other than medical literature which suggests that errors do occur.

Even assuming that petitioner had symptoms but failed to complain of them in the post-vaccination period, the undersigned agrees with Dr. Evans' conclusion that, "any of these practitioners would be expected to note if the patient had . . . significant left arm physical signs" or symptoms. Resp. Ex. C at 2. Based on experience and knowledge reviewing medical records, adjudicating vaccine cases, the evidence in the medical records, the expert opinions, and all of the evidence in this matter, the undersigned finds that petitioner's contemporaneous medical records provide accurate assessments of the petitioner's history and physical examinations. See Cucuras, 993 F.2d at 1528.

The undersigned also finds that petitioner's clinical course is not consistent with vaccine causation based on the case reports in the medical literature. Petitioner did not have brachial plexus neuritis as confirmed by both experts. He did not receive a rubella vaccine. He did not have an "abrupt onset of stiffness" in his hands or "marked synovial swelling over the wrists" as described in Hale and Ruderman. Resp. Ex. A-6 at 1. Moreover, he was not diagnosed with viral induced tenosynovitis, as the case report in Hale and Ruderman. Id.

For all of the reasons described above, the undersigned finds that petitioner has failed to provide preponderant evidence of a logical sequence of cause and effect.

iii. Althen Prong Three: Proximate Temporal Relationship

Under Althen Prong Three, petitioner must provide "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." De Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The acceptable temporal association will vary according to the particular medical theory advanced in the case. See Pafford, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that "a temporal relationship alone will not demonstrate the requisite causal link" and there must be "a medical theory causally connecting the vaccine and injury").

The onset of petitioner's peripheral neuropathy dates back to December 2012, when Dr. Hougen noted that petitioner had mild peripheral neuropathy. The onset of his CTS dates back to January 2014, when he injured his left wrist while lifting heavy boxes. His wrist was described as swollen and painful, and he had throbbing in his fingers. Examination revealed bruising and edema of petitioner's wrist and limited range of motion. He was diagnosed with left wrist trauma and possible rupture of the flexor carpi radialis tendon.

With regard to the onset of significant aggravation of petitioner's CTS and peripheral

neuropathy, Dr. Klein agreed that petitioner's symptoms became clinically apparent in March 2016. However, Dr. Klein disagreed that onset was that late. See Pet. Ex. 14 at 2-3. Instead, Dr. Klein opined that petitioner had a progressive onset, or there was a latency period that began after petitioner's October 2015 flu shot that did not manifest as clinically significant CTS until March 2016. Id. Alternatively, Dr. Klein attributed petitioner's delay in reporting his left arm complaints between the date of vaccination, October 8, 2015, and the first documentation of symptoms, March 28, 2016, on petitioner's decision to prioritize treatment of his other health problems over his left arm symptoms.

Dr. Evans opined that petitioner's onset was too long to be vaccine related. After reviewing the well-documented medical chronology post-vaccination, Dr. Evans concluded that the long delay between vaccination and first report of symptoms made a relationship to vaccination very unlikely.

The undersigned finds Dr. Evans' opinions to be more persuasive than Dr. Klein's, which are not well supported by the records. As noted by Dr. Evans, petitioner's left arm was examined six days after vaccination, but there was no reference to left arm symptoms, and no physical finding of left arm, forearm, or wrist swelling. No adverse reaction to the vaccine was noted. Twenty-five days after vaccination, petitioner complained of leg swelling, but there was no mention of left arm swelling, pain, or other CTS symptoms. Almost eight weeks (53 days) after vaccination, petitioner had a physical examination by a dermatologist. There was no reference to pain, vaccination, or swelling of the left arm, forearm, or wrist. Almost nine weeks (62 days) after vaccination, petitioner visited his primary care physician and complained of right shoulder pain, but there is no documentation of left arm pain, swelling, or paresthesias. Over four months (123 days) after vaccination, physical examination showed that petitioner had limited range of motion and crepitus in his right shoulder, but there was no mention of any problems in the left shoulder or arm, and no symptoms of CTS were documented.

The undersigned finds that the onset of petitioner's significant aggravation of CTS and peripheral neuropathy occurred approximately five months (169 days) after vaccination when he presented to Dr. Kakehashi with the complaint of "left arm pain and numbness." Pet. Ex. 2 at 283. Prior to that time, there is no evidence in the record that the petitioner experienced left arm pain, swelling, or paresthesia.

Further, the undersigned agrees with Dr. Evans that an onset of approximately five months is too long for there to be a temporal association between petitioner's flu vaccination and his alleged injuries. While neither expert provides a specific time frame within which onset would be expected, the medical literature does provide a helpful framework.

In the case reported by Hale and Ruderman, the rubella vaccine recipient complained of stiffness three weeks after vaccination. Resp. Ex. A-6 at 1. Six weeks (42 days) post-vaccination, she developed "marked synovial swelling" over both wrists. Id. In Ray, the researchers found no evidence of a causal association between the rubella vaccine and "persistent joint symptoms." Resp. Ex. A-9 at 4. While they did not find adverse reactions to be statistically significant, the authors did observe that six vaccinees had joint symptoms within six weeks of vaccination, including one diagnosed with CTS. Id. at 5. With regard to the rubella

vaccine, the postulated mechanism is viral induced tenosynovitis causing median neuropathy. Although the theory is different than that proposed by Dr. Klein, these studies provide some frame of reference with regard to temporal association between vaccines and onset of CTS.

An inflammatory mechanism was referenced by Tosti and Ilyas, although not in the context of vaccination. In cases of acute CTS, "onset of symptoms is on the order of hours to days following an initiating event. Patients will complain of pain and numbness over the median nerve distribution, and progressive stages may reveal weakness." Resp. Ex. A-11 at 4. Acute CTS is "characterized by rapid onset of median neuropathy caused by sudden increases in carpal tunnel pressures, which leads to ischemia of the median nerve. The most common cause is traumatic injury, although atraumatic sources should also be recognized." Id. at 5. Inflammatory causes of acute CTS include overuse, gout, and rheumatoid arthritis. Id. at 3 tbl.1. Thus, Tosti and Ilyas recognized an inflammatory mechanism, but described a fairly rapid onset when there is a specific triggering event.

Based on a review of all of the evidence, the undersigned finds that petitioner has failed to prove by preponderant evidence that an onset of symptoms occurring approximately five months after vaccination is an appropriate time frame for significant aggravation of CTS and peripheral neuropathy.

D. Standards for Adjudication—Significant Aggravation

Additional analysis is required to determine whether petitioner's vaccination significantly aggravated his pre-existing injury. The elements of an off-Table significant aggravation case are set forth in Loving. See also W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the Loving case provides the correct framework for evaluating off-table significant aggravation claims"). The Loving court combined the Althen test, which defines off-Table causation cases, with a test from Whitecotton. Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374 (Fed. Cir. 1994), rev'd sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995) (concerning on-Table significant aggravation cases). The resultant test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

E. Significant Aggravation Theory

i. Loving Prong 1: What Was Petitioner's Condition Prior to

Administration of the Vaccine?

The first step in the Loving test is to determine petitioner's condition with regard to peripheral neuropathy and CTS before he received the vaccination at issue. Here, the medical records show that petitioner was diagnosed with peripheral neuropathy as early as December 19, 2012 by Dr. Hougen. Pet. Ex. 2 at 161-66. Dr. Hougen notes petitioner's diabetes, "mild peripheral neuropathy" and "mild peripheral numbness," as well as his diminished peripheral sensation. Id. at 161, 163.

The onset of petitioner's CTS dates back at least to January 2014, when he injured his left wrist while lifting heavy boxes. Pet. Ex. 2 at 290. His wrist was described as swollen and painful, and he had throbbing in his fingers. Id. Examination showed bruising and edema of petitioner's wrist and limited range of motion. Id. at 291-92. He was diagnosed with left wrist trauma and possible rupture of the flexor carpi radialis tendon. Id. at 292.

Pre-vaccination records verify that petitioner had risk factors for both CTS and peripheral neuropathy, including diabetes, and congestive heart failure, which alters the fluid balance in the body. Pet. Ex. 9 at 4. Immediately prior to vaccination, the medical records do not reference left arm CTS or peripheral neuropathy.

ii. Loving Prong 2: What Is Petitioner's Current Condition (or His Condition Following the Vaccination, If Also Pertinent)?

The second part of the Loving test is to discuss "the person's current condition (or condition following the vaccination if that is also pertinent)." 86 Fed. Cl. at 144. Here, petitioner's condition following vaccination is most pertinent.

After petitioner received the flu vaccination, he did not report symptoms of CTS or peripheral neuropathy to his treating physicians for over five months. Multiple physicians performed physical examinations and treated Mr. Barlow between October 8, 2015 and February 2, 2016, however, none documented swelling, edema, bruising, numbness, or pain of petitioner's left shoulder, forearm, or wrist.

Following vaccination, and for months afterwards, the medical records do not reference left arm CTS or peripheral neuropathy.

iii. Loving Prong 3: Does Petitioner's Current Condition (or Condition After Vaccination) Constitute a "Significant Aggravation" of His Condition Prior to Vaccination?

The next prong of the Loving test is to determine whether there is a "significant aggravation" of petitioner's condition by comparing his condition before vaccination to his condition after vaccination. The statute defines "significant aggravation" as "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health." § 33(4).

As set forth earlier, there is no factual support in the contemporaneous medical records to support the type of edema or swelling associated with CTS or peripheral neuropathy occurred after vaccination. Petitioner, through his expert, failed to explain or show that his clinical course was consistent with a hypersensitivity reaction induced inflammation that aggravated petitioner's CTS or peripheral neuropathy. Dr. Klein does not point to any diagnostic tests, any facts, or any other evidence to show that petitioner's CTS or peripheral neuropathy occurred due to a hypersensitivity reaction.

The onset of petitioner's peripheral neuropathy dates back to December 2012, when Dr. Hougen noted that petitioner had mild peripheral neuropathy due to his diabetes, and the onset of his CTS dates back to January 2014, when he injured his left wrist while lifting heavy boxes. Petitioner's chronic condition is supported by the medical records, and there is no evidence of that an acute event, such as vaccination, exacerbated petitioner's condition.

iv. Loving Prong 4: Is There a Medical Theory Causally Connecting Such a Significant Worsened Condition to the Vaccination?

As set forth in Section V.C.i above, petitioner failed to establish by a preponderance of the evidence, a medical theory causally connecting petitioner's condition, or any significant aggravation. Therefore, petitioner failed to prove causation as to significant aggravation.

v. Loving Prong 5: Is There a Logical Sequence of Cause and Effect Showing That the Vaccination Significantly Aggravated Petitioner's Condition?

For the same reasons set forth in Section V.C.ii above, petitioner failed to prove by preponderant evidence a logical sequence of cause and effect showing that the vaccination significantly aggravated his condition.

vi. Loving Prong 6: What Is a Proximate Temporal Relationship Between the Vaccination and the Significant Aggravation?

The last element in the six-part Loving test has origins in Althen Prong 3. As stated in Loving, this element is "a showing of a proximate temporal relationship between vaccination and the significant aggravation." 86 Fed. Cl. at 144. Again, for the same reasons set forth in Section V.C.iii, petitioner failed to prove the third prong of Althen, which is the last element of the Loving test.

VI. CONCLUSION

It is clear from the medical records that Mr. Barlow suffered as a result of his illnesses, and the undersigned extends her sympathy to him. However, this case cannot be decided based upon sympathy but rather by an analysis of the evidence.

For all of the reasons discussed above, the undersigned finds that petitioner has not established by preponderant evidence that vaccination caused or significantly aggravated

petitioner's CTS or peripheral neuropathy. Therefore, petitioner is not entitled to compensation and his petition must be dismissed. In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master