In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-799
Filed: May 21, 2021

ASHOK PAHWA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Ruling on Entitlement; Table Injury; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Isaiah Richard Kalinowski, Maglio Christopher and Toale, PA, for Petitioner
Althea Walker Davis, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON ENTITLEMENT[1]

Oler, Special Master:

On June 14, 2017, Ashok Pahwa ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). Petitioner alleges that he suffered a shoulder injury related to vaccine administration ("SIRVA") following receipt of his September 15, 2015 influenza ("flu") vaccination. Pet. at 2-3, ECF No. 1. For the reasons articulated in this Ruling, I find that Petitioner is entitled to compensation.

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[1] This Ruling will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Ruling will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Ruling's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Ruling will be available to the public in its present form. *Id.*

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

I. Procedural History

On June 14, 2017, Petitioner filed his Petition alleging that the flu vaccination he received on September 15, 2016 caused him to suffer a SIRVA in his left arm. ECF No. 1. Petitioner filed four affidavits in support of his claim. Ex. 2; Ex. 9; Ex. 26; Ex. 27.

On March 20, 2018, Respondent's filed a Rule 4(c) Report stating that this case was not appropriate for compensation under the terms of the Vaccine Act. ECF No. 18.

On December 14, 2018, Petitioner filed an expert report from Dr. Sudhir Vaidya and the supporting medical literature. ECF No. 26, Ex. 10; ECF No. 26 Exs. 12-22.

On June 5, 2019, Respondent filed an expert report from Dr. Robert Brophy and the supporting medical literature. ECF No. 31, Ex. A, ECF. No. 31, Exs. A 1-2.

On June 25, 2019, I held a status conference with the parties and ordered Petitioner to file a status report and/or additional evidence relating to the issue of onset. ECF No. 32.

On July 25, 2019, Petitioner filed additional medical literature in support of his claim. ECF No. 33, Exs. 23-24.

On July 26, 2019, I ordered the parties to file a joint status report indicating whether they agreed to a ruling on the record. *See* non-PDF order dated 7/26/2019. On August 9, 2019, the parties filed a joint status report stating that it was appropriate for me to decide the case on the papers. ECF No. 36.

On August 30, 2019, I held a status conference with the parties and ordered Petitioner to file an affidavit addressing his delay in seeking treatment for his shoulder pain and a description of his physical activity before and after receiving the vaccination, along with any evidence to support the statements made therein. ECF No. 38. On October 23, 2019, Petitioner filed his third affidavit in support of his claim. ECF No. 39, Ex. 26.

On January 31, 2020, Petitioner filed his Motion for Findings of Fact and Conclusions of Law Regarding Entitlement to Compensation and his supporting memorandum. ECF. No. 42. On June 1, 2020, Respondent filed a Response to Petitioner's Motion for Findings of Fact and Conclusions of Law. ECF. No. 46. On June 4, 2020, Respondent filed the medical literature in support of his response. ECF. No. 47, Ex. C. On June 15, 2020, Petitioner filed his Reply to Respondent's Response to his Motion for Findings of Fact and Conclusions of Law Regarding Entitlement to Compensation. ECF No. 49.

On June 30, 2020, the parties filed a Joint Status Report stating that that they had nothing further to submit into evidence in this case, no further briefing to submit for the Court's consideration, and that the record was sufficiently complete for the Court to make a ruling on the disputed issues related to causation and entitlement to compensation. ECF No. 50.

On February 16, 2021, I issued an order referring this case to ADR. ECF No. 51. On April 6, 2021, Chief Special Master Corcoran issued an order concluding the ADR proceedings. ECF No. 52.

I held a status conference on April 21, 2021 where I informed Petitioner's counsel that Petitioner had not stated with specificity when his shoulder pain began in relation to his flu vaccination. *See* Scheduling Order dated April 21, 2021; ECF No. 53. I accordingly asked Petitioner to file an affidavit providing as much detail as he could concerning the specific onset of his pain. Petitioner filed his fourth affidavit on April 30, 2021. Ex. 27. This matter is now ripe for adjudication.

II. Medical Records

A. Relevant Pre-Vaccination History

Prior to his vaccination, Petitioner was a relatively healthy individual who saw his primary care physician, Dr. Sudhir Vaidya, sporadically with minor complaints. Dr. Vaidya's records list Petitioner's chronic diagnoses as dysthymic disorder, hyperlipidemia, and anxiety disorder. Ex. 2 at 13.

On January 21, 2011, Petitioner saw Dr. Vaidya complaining of left elbow pain that began one month prior. Ex. 5 at 4. Dr. Vaidya assessed him with tennis elbow and advised him to use aspercreme, to wear an ace bandage, and recommended an x-ray of his left elbow. *Id.* at 9.

On August 17, 2012, Petitioner saw Dr. Vaidya complaining of a dry cough that had persisted for about one month. Ex. 5 at 5. Dr. Vaidya prescribed hydrocodone syrup. *Id.* at 9.

On February 17, 2014, Patient saw Dr. Vaidya complaining of a chronic cough for the past six weeks. Ex. 5 at 8.

On May 10, 2014, Petitioner went to Delman Chiropractic Center. During this visit, Petitioner indicated he had lower back pain that started two days prior when he bent down to pick up his toothbrush. Ex 4 at 5. He rated his pain 3/10 and reported that the pain was intermittent, had decreased since it began, and had not affected his ability to work or to be active. *Id*.

On September 4, 2014, Petitioner saw Dr. Vaidya and indicated he had experienced ankle pain for the past month. Ex. 2 at 4. He reported that his ankle hurt occasionally, but not particularly after or during walking. *Id*. at 4. Dr. Vaidya recommended an x-ray of the left ankle, using an ankle support, and taking Tylenol for pain. *Id*.

On September 16, 2015, at the age of 60, Petitioner received a flu vaccination (Afluria) at CVS Pharmacy in Rye Brook, New York. Ex. 1 at 3.

B. Post-Vaccination History

On September 27, 2015, Petitioner saw his chiropractor for a cervical spine adjustment. Ex. 4 at 2.

On September 28, 2015, Petitioner saw Dr. Vaidya for a regular check-up. Ex. 2 at 5. He was concerned about nail ridges and reported that he had been seeing a psychiatrist for about six months. *Id*. There is no indication in this record that Petitioner mentioned experiencing shoulder pain.

On June 30, 2016, Petitioner saw Dr. Vaidya complaining of weakness in his left shoulder after he received his flu shot. Ex. 2 at 14. He wanted Dr. Vaidya to see whether the weakness was related to his flu vaccination. *Id*. Petitioner reported a reduced range of motion and that his shoulder ached sometimes while sitting and sometimes while lifting weight. *Id*. He rated the aching as 4-5/10. *Id*. He was not experiencing any numbness or tingling. *Id*. Dr. Vaidya assessed Petitioner with deltoid palsy secondary to flu injection and noted that Petitioner was not receptive to physical therapy. *Id*. Dr. Vaidya advised Petitioner to exercise at home and to return for a follow up if the weakness progressed. *Id.*

On September 15, 2016, Petitioner returned to Dr. Vaidya for a follow-up concerning his left shoulder weakness. Petitioner reported that the weakness had not changed and that "it may be worse." Ex. 2 at 17. He also reported a pulsatile pain that was transient. *Id*. Dr. Vaidya assessed Petitioner with deltoid paresis secondary to flu injection and noted that Petitioner's pain was worsening. *Id*. Dr. Vaidya recommended home exercises and referred Petitioner to Dr. Karen Pechman for an electrodiagnostic study. *Id*. Petitioner asked whether it was safe for him to get another flu shot. *Id*. Dr. Vaidya noted, "In my judgment, flu shot should be OK. This was a rare complication due to inflammation of nerve rather than allergy to flu shot. It is not like GBS, or allergy [] to eggs." *Id.*

On March 3, 2018, Petitioner saw Dr. Vaidya for a follow up appointment related to bilateral knee pain that began two months prior when he started playing pickleball. Ex. 8 at 2. Dr. Vaidya referred Petitioner to an occupational therapist and recommended an x-ray of both knees. *Id*. at 3.

On July 24, 2018, Petitioner saw Dr. Pechman for an EMG study of the left upper extremity to investigate for nerve entrapment syndrome, radiculopathy, peripheral neuropathy, mononeuritis, or other cause of his symptoms of pain, tingling, numbness, weakness and dysfunction in the left upper extremity. Ex. 7 at 1. On physical examination, Dr. Pechman found "deep tendon reflexes measured 2+ throughout. Manual muscle testing was within normal limits. Sensation was intact to light touch. There was no evidence of scapular winging." *Id*. Dr. Pechman interpreted the EMG results as evidence of left cervical radiculopathy. *Id*.

On November 18, 2018, Petitioner reported to Dr. Vaidya that his condition had not improved. Vaidya Rep. at 2. He was still having pain and a limited range of motion in his left shoulder. *Id*. Dr. Vaidya conducted a physical evaluation and found that Petitioner had no point tenderness over the shoulder and pain and restriction on the last few degrees of abduction. *Id*. Dr.

Vaidya conducted a Hawkins test, Neer test, Empty Can test, O'Brien's test, and a Speed test, the results of which were all positive, indicating chronic bursitis and capsulitis.[3] *Id.*

III. Affidavits of Petitioner

Petitioner filed a total of four affidavits: one attesting to the facts alleged in his petition, the second a more detailed description of his injury and its effects, a third and fourth after being ordered to provide additional evidence relating to the issue of onset. Ex 2; Ex. 9; Ex 26; Ex. 27.

Petitioner describes himself as simple and old-fashioned: "the sort of person who does not go to the doctor or make use of artificial medical treatments if I do not absolutely need to." Ex. 26 at 1. He did not get vaccinated every year because he tried to avoid medicines or other medical treatments unless necessary. Ex. 9 at 1. Prior to the vaccination at issue in this case, his overall health was good, with the exception of having high cholesterol. Ex. 9 at 1; Ex. 26 at 1.

Petitioner received a seasonal influenza vaccination at CVS drug store in Rye Brook, New York on September 16, 2015, because his doctor "was rather persistent and convinced me that it was important because I was over the age of 50." Ex. 2 at 1; Ex. 9 at 1. He alleges that as a result of that flu vaccination he sustained a "shoulder injury related to vaccination administration (SIRVA) and its sequelae, which were actually caused by the vaccine administered, and I suffered the residual effects or complications of the above condition for more than six months following the administration of that vaccination." Ex. 9 at 2.

After vaccination, he "experienced soreness in [his] left shoulder area, where the vaccination had been injected." Ex. 9. at 2. The pain began immediately after vaccination. Ex. 27. Like with other vaccinations, Petitioner believed the soreness would dissipate with time and shoulder exercises. *Id.* He chose to "work through it." Ex. 26 at 1. He did not seek medical attention because "it felt silly to go to a doctor for something like this." Ex. 9 at 2. He stated, "I don't pop an Advil at the first sign of pain." Ex. 26 at 1.

Petitioner expected the pain would dissipate. Ex. 27 at 2. He was busy with work which required constant travel. *Id.* He stated, "[m]y travel schedule for work made it very inconvenient to go see a doctor about something I wished would just go away on its own." *Id.*

Petitioner did not become concerned until an abnormal amount of time had passed, and the pain persisted. Ex. 26 at 2. The pain became more severe and Petitioner noticed that he was favoring his injured shoulder and making subconscious adjustments when performing routine tasks. Ex. 9 at 2; Ex. 26 at 2; Ex. 27 at 2. After several months had passed, he decided to Google his symptoms. Ex. 9 at 2. He was "taken aback when Google auto-completed [his] query when [he] was only halfway done typing it in." *Id.* After he learned about this "serious complication related to the administration of a flu shot," he was worried and made appointment to see Dr. Vaidya on June 30, 2016. *Id.*

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[3] Petitioner did not file a medical record for the November 18, 2018 appointment with Dr. Vaidya. The details of that appointment were discussed by Dr. Vaidya in his expert report.

Prior to his flu vaccination, Petitioner did not exercise regularly, but he did enjoy hiking, and gardening. Ex. 26 at 1. After his vaccination, Petitioner claims the injury affected his work and personal life. He had to travel often for work, and he had trouble lifting his luggage into the overhead compartments on airplanes. Ex. 9 at 2. Petitioner claims that the injury also affected routine tasks such as driving, performing household chores, carrying groceries, picking up his 18-month old granddaughter, and his ability to work out. *Id.* He eventually canceled his gym membership and hired a landscaper to maintain his garden. *Id.* at 2-3. He could no longer participate in hikes that involved rock scrambling. *Id.* at 2.

Petitioner stated that "the shoulder discomfort has become a part of [his] life," and he simply adjusts to it. Ex. 26 at 2. He "never contemplated that a vaccination could cause pain and restriction of movement for months and even years on end." *Id.* at 1. He continues to worry about the future, and "whether it will get worse and limit my ability to perform certain tasks." *Id.* at 2.

IV. Expert Opinions and Qualifications

A. Petitioner's Expert: Dr. Sudhir Vaidya

Dr. Sudhir Vaidya is Petitioner's treating Family Medicine/Sports Medicine specialist. Vaidya Rep. at 1. He is a Diplomate of the American Board of Family Practice with a Certificate in Sports Medicine, a Diplomate of the American Academy of Pain Management, a Diplomate of the American Board of Pain Medicine, and he is a Certified Hyperbaric and Wound Specialist. Ex. 11 at 1 (hereinafter "Vaidya CV"). Dr. Vaidya earned his Bachelor of Medicine and Bachelor of Surgery from Karnataka Medical College in Hubli, India. Vaidya CV at 1. He served as a Post Graduate Resident in Anesthesiology at SSG Hospital and Medical College in Baroda, India, and a Fellow of the Royal College of Surgeons of Glasgow. *Id.* at 1-2. He has also subsequently completed residencies in emergency medicine, spinal injuries and rehabilitation, and orthopedics. *Id.* at 2-3. He currently serves as the Director of Sports Medicine and Pain Management at Burke Rehabilitation Hospital and is a Clinical Associate Professor of Family and Community Medicine at New York Medical College in Valhalla, New York. *Id.* at 1. Dr. Vaidya has published a handful of articles on a variety of topics and has given a number of presentations on the topic of Pain Management. *Id.* at 3-5.

Dr. Vaidya has performed all evaluations and care of Petitioner's shoulder injury since 2016. Vaidya Rep. at 1. He reports that prior to the 2015 flu vaccination, Petitioner had no problems with his shoulder. *Id*. He concedes that he saw Petitioner two weeks after his flu vaccination, but there was "no mention in that visit's notes regarding symptoms in his shoulder." *Id*.

The first time Petitioner complained to Dr. Vaidya of his shoulder injury was on June 30, 2016, when he asked Dr. Vaidya whether his symptoms were related to his vaccination. Vaidya Rep. at 1-2. Upon examination, Dr. Vaidya determined that Petitioner was suffering from a deltoid injury secondary to his intramuscular influenza injection. *Id.* at 2. Because Petitioner was not interested in outpatient physical therapy, Dr. Vaidya instructed him on how to perform home exercises aimed at addressing his symptoms. *Id*.

On September 15, 2016, when Petitioner returned, Dr. Vaidya presumed that he was suffering from deltoid paresis due to nerve inflammation and recommended electrodiagnostic studies to assess nerve damage. Vaidya Rep. at 2. Despite his initial suspicion, the EMG results did not reveal "any evidence that would support a neurologic etiology for [Petitioner's] injury. *Id*.

Dr. Vaidya did not see Petitioner again until November 13, 2018.[4] Vaidya Rep. at 2. Petitioner was still complaining of pain and limitation of movement, and he rated his pain as 5/10. *Id*. Dr. Vaidya performed a number of tests and concluded that his symptoms were consistent with chronic shoulder bursitis and capsulitis. *Id*. Petitioner was not willing to undergo any invasive studies or surgical intervention "as the risk associated with procedures do not outweigh the questionable benefits." *Id*. at 2-3. Dr. Vaidya is of the opinion that Petitioner has not had any improvement in his shoulder since his injury in 2015. *Id*. at 3.

According to Dr. Vaidya, Petitioner's "reduced passive range of motion of the shoulder is consistent with adhesive capsulitis, which can occur following shoulder injury related to vaccine administration," and there have been no intervening explanations for his symptoms following vaccination. Vaidya Rep. at 3-4. "There was no prior injury or chronic condition that would explain his injury symptoms, and no contemporaneous traumatic injury (other than the vaccination) that would explain it either." *Id*. at 4. Thus, it is Dr. Vaidya's opinion, that "to a reasonable degree of probability [Petitioner] suffered from a shoulder injury related to vaccine administration." *Id*. at 3. "No other condition explains [Petitioner]'s pain or loss of range of motion in the shoulder which occurred following his flu vaccination." *Id*. at 4

B. Respondent's Expert: Dr. Robert Brophy

Dr. Robert Brophy is a Professor of Sports Medicine at Washington University School of Medicine in St. Louis, Missouri, specializing in shoulder and knee injuries. Ex. B at 1 (hereinafter "Brophy CV"). He is licensed to practice medicine in the state of Missouri and is a diplomate of the American Board of Orthopedic Surgery with a Certificate of Added Qualifications in sports medicine. Brophy CV at 1. Dr. Brophy earned his medical degree at Washington University School of Medicine, and subsequently completed an internship in orthopedic surgery/general surgery at New York Presbyterian Hospital in New York, New York, followed by a residency in orthopedic surgery and a fellowship in sports medicine/shoulder surgery at the Hospital for Special Surgery in New York, New York. *Id.* Dr. Brophy has published a multitude of articles in peer reviewed publications, frequently gives presentations on the topic of sports related injuries and has been the recipient of numerous honors and awards. Brophy CV at 2-3, 6-31.

Dr. Brophy agreed that Petitioner "did suffer from adhesive capsulitis in his left shoulder." Brophy Rep. at 4. However, he did not agree that the flu vaccine Petitioner received on September 6, 2015, caused or materially contributed to Petitioner's injury. His report is devoted to whether a vaccination can cause adhesive capsulitis.

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[4] It does not appear that the medical record for this visit was filed in the record.

Based on Dr. Brophy's review of the records, Petitioner suffers from "[i]diopathic adhesive capsulitis, commonly known as frozen shoulder, [which] has an overall incidence of 3 to 5 percent, peaking between the ages of 35 to 65." Brophy Rep. at 2; *see also* Lamplot et al., *Outcomes From Conservative Treatment of Shoulder Idiopathic Adhesive Capsulitis and Factors Associated With Developing Contralateral Disease*, 6 THE ORTHOPAEDIC JOURNAL OF SPORTS MEDICINE, (2018) (filed as Ex. A-1). The origin of idiopathic adhesive capsulitis is unknown and "the disease typically follows a three phase course: (1) "freezing" phase over three to nine months with progressive loss of motion; (2) "frozen" phase lasting four to 12 months with stable loss of motion; and, (3) "thawing" phase with improving motion over one to four years." *Id*. at 2-3. Dr. Brody opined that the following statement by Dr. Vaidya perfectly describes idiopathic adhesive capsulitis: "There was no prior injury or chronic condition that would explain his injury symptoms, and no contemporaneous traumaticinjury... that would explain it." *Id*. at 4.

Finally, Dr. Brophy indicated that "there is limited evidence that a flu shot can cause adhesive capsulitis." Brophy Rep. at 3. Dr. Brophy claimed that "all of the cases reported in the literature report a temporal association between administration of a vaccine and subsequent development of adhesive capsulitis;" however, "temporal association does not equate with causation." *Id*.

V. Parties' Contentions

In sum, Petitioner argues he has satisfied the criteria to establish a Table claim for SIRVA. Pet. Mot. at 2. Alternatively, Petitioner argues that he has met the burden for establishing an "off-Table" injury. § 11(c)(1)(C)(ii). Pet. Mot. at 5.

Respondent argues that Petitioner's contemporaneous records do not establish that his injury manifested within a medically appropriate time frame for either an on-Table or off-Table claim. Resp't's Resp. at 13, 20. Respondent argues that there is no evidence establishing the onset of Petitioner's shoulder pain in either his affidavits or the contemporaneous medical records. *Id*. Respondent further argues that Petitioner has not offered a reliable expert opinion establishing that Petitioner's initial pain resulted from poor injection technique or an immune-mediated inflammatory response and has not established that his flu vaccine in fact caused his shoulder symptoms. *Id*. at 21. Accordingly, Respondent argues Petitioner's claim should be denied.

VI. Applicable Law

A. Petitioner's Overall Burden in Vaccine Program Cases

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. § 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. § 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id*.

To resolve factual issues, the special master must weigh the evidence presented, which may

include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at 3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at 5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement, a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he received. § 11(c)(1)(C).

The most recent version of the Table identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). Pursuant to the Table, SIRVA is defined as:

> shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known).

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
> (ii) Pain occurs within the specified time-frame;
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3.

If, however, petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, he must prove that the administered vaccine caused his injury to receive Program compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove his claim by preponderant evidence. § 13(a)(1)(A). The Federal Circuit has held that to establish an off-Table injury, petitioner must "prove ... that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Hum. Servs*., 165 F.3d 1344, 1351 (Fed. Cir 1999).

The Federal Circuit has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury' to establish that the vaccine was a substantial factor in bringing about the injury." *Shyface*, 165 F.3d at 1352-53 (*quoting Grant v. Sec'y of Health & Hum. Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). The Federal Circuit added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required to show by preponderant evidence that the vaccination brought about his injury by providing:

(1) a medical theory causally connecting the vaccination and the injury;
(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
(3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id*. at 1280.

VII. Findings of Fact

Respondent does not dispute that Petitioner received the vaccine alleged as causal in his left deltoid on September 16, 2015, that he suffered the residual effects of his injury for more than six months, or that he has satisfied the majority of the QAI requirements for a Table SIRVA. Rather, the primary disagreement in this case involves the timing of the onset of Petitioner's left shoulder injury.

A. Prior Condition

The first requirement under the QAIs for a Table SIRVA is a lack of a history revealing problems associated with the affected shoulder which were experienced prior to vaccination and would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i).

Although the medical records in this case are limited, they provide a comprehensive picture of Petitioner's condition prior to and at the time of his vaccination. The medical records establish

that Petitioner did not seek medical treatment often, and that his only chronic conditions were dysthymic disorder, hyperlipidemia, and anxiety disorder. Ex. 2 at 13. Respondent did not identify any prior issue associated with Petitioner's left shoulder and has not argued that Petitioner has failed to satisfy this requirement.

There is no evidence that Petitioner experienced any issues involving his left shoulder prior to vaccination.

B. Onset of Pain

In order to meet the definition of a Table SIRVA, Petitioner must demonstrate that he experienced onset of pain within 48 hours of vaccination. This is the only requirement of a Table SIRVA claim which Respondent maintains that Petitioner has failed to satisfy.

I find that the medical records, when viewed in conjunction with Petitioner's affidavits, provide preponderant evidence that Petitioner experienced pain within 48 hours of his vaccination.

In his affidavit filed on April 30, 2021, Petitioner averred that he experienced pain immediately after his vaccination. Ex. 27 at 1. Petitioner further stated that this pain never went away. *Id.* at 2. After the pain persisted and Petitioner began to adjust his behavior to accommodate his painful shoulder, he made a medical appointment. *Id.*

On June 30, 2016, Petitioner visited Dr. Vaidya. During this appointment, he complained of weakness in his left shoulder that began "following flu shot." Ex. 2 at 14. Dr. Vaidya assessed Petitioner with deltoid palsy secondary to flu injection. *Id.* Petitioner saw Dr. Vaidya again on September 15, 2016 for a follow-up concerning his left shoulder weakness. Although the records from this visit do not discuss onset of pain, it is apparent that Petitioner still attributed his shoulder pain to his flu shot. Dr. Vaidya assessed Petitioner with deltoid paresis secondary to flu injection and noted that Petitioner's pain was worsening. Ex. 2 at 17.

Respondent has raised two main issues with respect to Petitioner's evidence in this case. First, he stressed that although Petitioner claims to have experienced pain in his left shoulder where the vaccine was injected, he did not mention his shoulder pain to his primary care physician two weeks later on September 28, 2015. "Rather, he discussed nail ridges and a psychiatry appointment that had taken place six months earlier." Resp't's Resp. at 9-10. In addition, Respondent cited the length of time that lapsed before Petitioner sought medical care for his left shoulder pain. Resp't's Resp. at 11. After the September 16, 2015 vaccination, Petitioner was not seen for his left shoulder injury until nine-and-one-half months later, on June 30, 2016.

With respect to the first issue, Petitioner stated right after he received the vaccine that, "it was not apparent to me at that time that this pain was out of the ordinary. I could not distinguish between what might be the soreness that typically accompanies vaccination in contrast to abnormal pain that I should have been more attentive to." Ex. 27 at 1. He assumed the pain would resolve

on its own. Petitioner's first post-vaccination visit with Dr. Vaidya took place on September 28, 2015, 13 days after vaccination.

In weighing medical records, "it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Gentile v. Sec'y of Health & Hum. Servs.*, No. 16-980V, 2018 WL 6540025, at 7 (Fed. Cl. Spec. Mstr. Oct. 29, 2018), *quoting Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam* 968 F.2d 1226 (Fed. Cir. 1992). The Federal Circuit recently rejected as incorrect "the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, No. 2020-2064, 2021 WL 2006226, (Fed. Cir. 2021). Rather, the court noted that while a patient is motivated to be truthful about his medical condition with his doctors, "that does not mean he will report every ailment he is experiencing…" *Id.* In this case, Petitioner did not disavow shoulder pain, but instead did not mention it at this September 28, 2015 appointment. I find Petitioner's explanation for why he did not report his shoulder pain just under two weeks after vaccination to be credible: namely, he assumed it was pain associated with the shot and that it would resolve by itself.

With respect to the second issue, Petitioner explained why he waited for more than nine months to seek medical attention for his shoulder. He stated that he believed and hoped the pain would subside on its own. In addition to this, Petitioner indicated that he was also extremely busy with work. He traveled frequently (and had amassed more than eight million frequent flyer miles). Ex. 26 at 2. Once Petitioner determined that his left shoulder pain was not improving, he performed an internet search,[5] became worried, and decided to see Dr. Vaidya. Ex. 9 at 2.

Respondent also stressed that when Petitioner finally did see Dr. Vaidya in June 2016, he did not specifically indicate that his left shoulder pain started within 48 hours of vaccination. Resp't's Resp. at 10. However, Petitioner reported left shoulder weakness and achiness "following his flu shot." Ex. 2 at 14. He specifically inquired as to whether his symptoms were related to the flu shot. *Id*. When he returned to Dr. Vaidya on September 15, 2016, Petitioner asked whether it was safe for him to get another flu shot. *Id*. at 17. Petitioner's third affidavit states that he "felt the discomfort after the injection in my shoulder." Ex. 26 at 1. His fourth affidavit specifically stated that he experienced pain immediately after vaccination. Ex. 27. Petitioner clearly links the onset of his left shoulder pain to the influenza vaccination he received, signifying immediate onset.

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[5] Respondent referenced Petitioner's internet search as evidence which undermines his claim of a SIRVA injury, remarking "Petitioner also likely discovered that compensation was being paid for such injuries." ECF No. 46. at 10. However, as noted by Chief Special Master Corcoran in *Smallwood v. Sec'y of Health & Hum. Servs.*, "[i]t is often common for a SIRVA petitioner to delay[] treatment, thinking his/her injury will resolve on its own. . . . [I]t is logical to assume Petitioner may have discounted his shoulder injury until educating himself through internet research regarding SIRVA." No. 18-0291V, 2020 WL 2954958, at 10 (Fed. Cl. Spec. Mstr. Apr. 29, 2020); *see also Gentile*, 2018 WL 6540025 at *7 (finding that Petitioner's delay in seeking treatment because she hoped her injury would resolve itself is not unusual among individuals experiencing SIRVA); *Tenneson v. Sec'y of Health & Hum. Servs*, No. 16-1664V, 2018 WL 3083140, at 5 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) (finding that the circumstances surrounding Petitioner's flu vaccination and her failure to seek treatment for six months reflect a pattern of treatment consistent with and similar to many other SIRVA claims).

Based upon the above, I find there is preponderant evidence which establishes that the onset of Petitioner's left shoulder pain began within 48 hours of vaccination.

C. Scope of Pain/Limited Range of Motion and Other Conditions

To establish a Table SIRVA, Petitioner's pain and reduced ROM must be limited to the shoulder in which the vaccination was administered. 42 C.F.R. § 100.3(c)(10)(iii).

Based on the medical records filed, Petitioner's only other complaint of pain was in 2018, when he had a follow up appointment with Dr. Vaidya related to bilateral knee pain that began two months prior when he started playing pickleball. Ex. 8 at 2. Accordingly, in connection with his flu vaccination, there is no indication that Petitioner experienced pain or limited ROM in any area other than his left shoulder. I note this is a point that Respondent does not dispute.

I find that the evidence demonstrates that Petitioner's pain and reduced ROM were limited to his left shoulder.

D. No Other Condition or Abnormality is Present that Would Explain Petitioner's Symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

The final requirement to establish a Table SIRVA is that no other condition or abnormality is present that would explain Petitioner's symptoms. 42 C.F.R. § 100.3(c)(10)(iii). Although Petitioner never did report any numbness or tingling to Dr. Vaidya, Dr. Vaidya presumed that Petitioner's condition was neurologic in nature given that his pain had not improved (and was perhaps worsening), more than a year after receiving the influenza vaccination. Vaidya Rep. at 2. Suspecting that Petitioner was suffering from deltoid paresis, Dr Vaidya referred Petitioner to Dr. Pechman for EMG testing in September of 2016. *Id*. The results of that testing, performed in June of 2018, revealed evidence of cervical radiculopathy. Ex. 7 at 1.

Cervical radiculopathy is defined as "radiculopathy of cervical nerve roots, often with neck or shoulder pain; compression of nerve roots is a common cause in this area." *Dorland's Illustrated Medical Dictionary* (33 ed. 2019), https://www.dorlandsonline.com/dorland/ definition?id= 101392&searchterm=cervical+radiculopathy (last visited May 12, 2021) (hereinafter "Dorland's"). Radiculopathy is defined as "disease of the nerve roots, such as from inflammation or impingement by a tumor or a bony spur." Dorlands, https://www.dorlandsonline.com/dorland/ definition? id=42742 (last visited May 12, 2021).

Neither party discussed the characteristics of cervical radiculopathy in their briefs or expert reports, and no medical literature was filed on this issue. A review of other Vaccine Program cases involving diagnoses of cervical radiculopathy reveals that cervical radiculopathy is a compression or structural issue associated with congenital or degenerative disease rather than an inflammatory condition. *Devonshire v. Sec'y of the Dep't of Health & Hum. Servs.*, No. 99-031V, 2006 WL 2970418, at *18 (Fed. Cl. Spec. Mstr. Sept. 28, 2006), *aff'd, Devonshire v. Sec'y of Dep't of Health & Hum. Servs.*, 76 Fed. Cl. 452 (2007). Neck pain and sensory loss can be symptoms of cervical radiculopathy, as well as symptoms of pain, tingling and numbness radiating up and down the arm

and hand. *See, e.g.*, *Kirby v. Sec'y of Health & Hum. Servs.*, No. 16-185V, 2019 WL 6336026, at *10 (Fed. Cl. Spec. Mstr. Nov. 1, 2019), *review granted, decision rev'd*, 148 Fed. Cl. 530 (2020), *reinstated*, No. 2020-2064, 2021 WL 2006226 (Fed. Cir. May 20, 2021); *Tomsky v. Sec'y of Health & Hum. Servs.*, No. 17-1132V, 2020 WL 5587365, at *4 (Fed. Cl. Spec. Mstr. Aug. 24, 2020); *Wallace v. Sec'y of Health & Hum. Servs.*, No. 16-1472V, 2019 WL 4458393, at *2 (Fed. Cl. Spec. Mstr. June 27, 2019); *Gurney*, 2019 WL 2298790 at *6.

In this case, Petitioner's medical records do not contain any references to neck pain, sensory loss, tingling or numbness radiating up and down his left arm and hand, either prior to or after his influenza vaccination. The medical records do not contain evidence of any other trauma or inciting event that would explain Petitioner's sudden onset of pain on September 15, 2015. After Petitioner received the flu vaccination, there is no evidence that Petitioner's pain ever relented, that his range of motion ever improved, or that Petitioner ever attributed his left shoulder pain to some subsequent or superseding event.

The EMG results were presumably available to Dr. Vaidya when he next saw Petitioner on November 13, 2018, still complaining of pain and limited range of motion. Vaidya Rep. at 2. Upon examination, Dr. Vaidya found pain and restriction on the last few degrees of abduction, and the results of Hawkins, Neer, O'Brien's, and Speed testing performed by Dr. Vaidya were all positive - indicating chronic shoulder bursitis and capsulitis. *Id*. Thus, despite his initial suspicion, Dr. Vaidya "did not find any evidence that would support a neurologic etiology for Petitioner's injury." Vaidya Rep. at 4. Petitioner "exhibited a reduced passive range of motion of the shoulder, consistent with adhesive capsulitis, which can occur following shoulder injury related to vaccine administration, but not with radiculopathy." *Id*. at 3-4.

Neither Respondent nor Dr. Brophy responded to Dr. Vaidya's opinion, or otherwise addressed the 2018 EMG test results.[6] As noted earlier, Dr. Brophy agreed that Petitioner "did suffer from adhesive capsulitis in his left shoulder." Brophy Rep. at 4. As a Diplomate of the American Board of Family Practice with a Certificate in Sports Medicine, I find that Dr. Vaidya is sufficiently qualified to evaluate Dr. Pechman's EMG report in connection with Petitioner's clinical manifestations of pain and limited range of motion, and I am therefore persuaded by Dr. Vaidya's assessment that cervical radiculopathy does not explain Petitioner's symptoms.

VIII. Conclusion

Based on the record as a whole, I find by preponderant evidence that Petitioner had no prior history of pain or dysfunction in the affected shoulder, the onset of Petitioner's left shoulder pain was within 48 hours of vaccination, his pain and reduced range of motion were limited to the shoulder in which the vaccine was administered, and no other condition of abnormality exists that would explain Petitioner's shoulder pain. Therefore, Petitioner has satisfied the requirements for a Table SIRVA and is entitled to compensation. An order regarding damages will issue shortly.

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[6] I note that in arguing against a Table SIRVA claim, Respondent did not argue in his brief that Petitioner's EMG results demonstrate that Petitioner had another condition or abnormality that would explain his shoulder pain.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master